

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

GEORGE LEHMANN and INSURED  
BENEFIT PLANS, INC., Individually and on  
Behalf of All Others Similarly Situated,

Lead Plaintiffs,

v.

OHR PHARMACEUTICAL INC., JASON  
SLAKTER, SAM BACKENROTH, and IRACH  
TARAPOREWALA,

Defendants.

No. 1:18-cv-01284-LAP

CLASS ACTION

JURY TRIAL DEMANDED

ECF CASE

**AMENDED CLASS ACTION COMPLAINT**

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**TABLE OF DEFINED TERMS AND ABBREVIATIONS**

<b>TERM</b>	<b>DEFINITION</b>
<b>Backenroth</b>	Sam Backenroth, Ohr's CFO from April 12, 2010 to the present
<b>BCVA</b>	Best Corrected Visual Acuity
<b>CEO</b>	Chief Executive Officer
<b>CFO</b>	Chief Financial Officer
<b>Classic Lesions Results</b>	The IMPACT Trial's final visual acuity results for the 70 patients with classic-containing CNV lesions, announced on March 27, 2015
<b>Class Period</b>	April 8, 2014 to January 4, 2018
<b>Class</b>	Subject to certain exceptions, all persons and entities who purchased or otherwise acquired Ohr common stock in the United States or on the NASDAQ Capital Market between April 8, 2014 and January 4, 2018, inclusive
<b>CMO</b>	Chief Medical Officer
<b>CNV</b>	Choroidal Neovascularization
<b>Company</b>	Ohr Pharmaceutical, Inc.
<b>Corporate Profile</b>	Corporate Profile, LLC
<b>CSO</b>	Chief Scientific Officer
<b>Defendants</b>	Ohr Pharmaceutical, Inc.; Irach Taraporewala; Jason S. Slakter, M.D.; and Sam Backenroth
<b>ETDRS</b>	Early Treatment Diabetic Retinopathy Study
<b>EVIZON</b>	Name for Squalamine when it was being tested by Genaera prior to 2009

**TABLE OF DEFINED TERMS AND ABBREVIATIONS**

<b>TERM</b>	<b>DEFINITION</b>
<b>Exchange Act</b>	The Securities Exchange Act of 1934, 15 U.S.C. §§ 78, et al.
<b>FDA</b>	United States Food and Drug Administration
<b>Genaera</b>	Genaera Corporation
<b>Genentech</b>	Genentech Inc.
<b>IMPACT Trial</b>	Ohr's phase II trial for Squalamine, also known as OHR-002
<b>Interim Results</b>	The IMPACT Trial's visual acuity results for the first 62 patients enrolled in the trial, announced on June 24, 2016
<b>Kaiser</b>	Peter K. Kaiser, M.D., Ohr's Head of Product Development from May 2014 to the present
<b>Lead Plaintiffs</b>	George Lehmann and Insured Benefits Plans, Inc.
<b>Lucentis</b>	Lucentis® a/k/a ranibizumab
<b>Lucentis Monotherapy Arm</b>	The control arm of the IMPACT Trial where patients self-administered placebo eye drops twice daily and received Lucentis injections as needed
<b>MAKO Trial</b>	Ohr's Phase III trial for Squalamine
<b>Occult Lesions Results</b>	The IMPACT Trial's final visual acuity results for the 94 patients with occult lesions less than 10 mm <sup>2</sup> , announced on May 11, 2015
<b>Ohr</b>	Ohr Pharmaceutical, Inc.
<b>PRN</b>	Pro Re Nata
<b>SEC</b>	United States Securities and Exchange Commission
<b>SKS</b>	SKS Ocular LLC

**TABLE OF DEFINED TERMS AND ABBREVIATIONS**

<b>TERM</b>	<b>DEFINITION</b>
<b>Slakter</b>	Jason S. Slakter, M.D., Ohr's CEO from August 7, 2015 to the present
<b>Squalamine Arm</b>	The treatment arm of the IMPACT trial where patients self-administered Squalamine eye drops twice daily and received Lucentis injections as needed
<b>Standard Eye Chart</b>	The Early Treatment Diabetic Retinopathy Study scale, which is characterized by lines of five letters each decreasing in size, which is used to measure visual acuity.
<b>Study 209</b>	A Genaera phase II trial for Squalamine, which was commenced in 2006
<b>Study 212</b>	A Genaera phase II trial for Squalamine, which was commenced in 2007
<b>Taraporewala</b>	Irach Taraporewala, Ohr's CEO from April 12, 2010 to August 6, 2015
<b>VEGF</b>	Vascular Endothelial Growth Factor
<b>Vista</b>	Vista Partners, LLC
<b>Wet AMD</b>	Wet Age-Related Macular Degeneration

**GLOSSARY**

<b>TERM</b>	<b>MEANING</b>
<b>Baseline</b>	In Wet AMD trials, this is the number of letters a patient reads before treatment is applied. This number is then compared to the number of letters a patient reads after treatment is applied to determine whether visual acuity has increased, stabilized, or decreased over time.
<b>Best Corrected Visual Acuity (“BCVA”)</b>	Measurement of the best vision correction that can be achieved.
<b>Choroidal Neovascularization (“CNV”)</b>	The growth of new blood vessels from the choroid layer of the eye into the macula.
<b>Classic CNV Lesions</b>	CNV lesions that have a demarcated border, are more aggressive, and cause early vision loss.
<b>Clinically Meaningful</b>	Term for whether a medical treatment provides a meaningful benefit on an aspect of how a patient feels, functions, or survives, as a result of treatment. In Wet AMD treatment, vision must improve by 4 letters according to the Standard Eye Chart to be considered clinically meaningful.
<b>Control Arm</b>	A group of patients in a clinical trial who do not receive the new treatment under study in order to compare the treatment to receiving no treatment or the standard of care.
<b>Early Treatment Diabetic Retinopathy Study (“ETDRS”)</b>	The standard eye chart used by doctors, which is characterized by lines of five letters each decreasing in size.
<b>IMPACT Trial</b>	Ohr’s phase II trial of Squalamine in patients with Wet AMD.
<b>Intravitreal Injection</b>	Injection of solution made directly through the eye into the center of the eyeball.
<b>Lesion</b>	In Wet AMD patients, an area of abnormal blood vessels and altered tissue.
<b>Lucentis®</b>	An FDA-approved agent manufactured by Genentech which inhibits the VEGF protein in the eye and serves as the current standard of care for patients with Wet AMD.

**GLOSSARY**

<b>TERM</b>	<b>MEANING</b>
<b>Macula</b>	Region of the retina responsible for central vision.
<b>MAKO Trial</b>	Ohr's phase III trial of Squalamine in patients with Wet AMD.
<b>Monotherapy</b>	The use of a single drug to treat a disease or condition.
<b>Occult CNV Lesions</b>	CNV lesions with a diffuse, poorly-defined border and often present with long-term maintenance of vision.
<b>Phase II Trial</b>	Clinical trials which are conducted in patients to determine whether the drug is effective and how long the effect lasts in patients.
<b>Phase III Trial</b>	Clinical trials that are conducted in a broader number of patients to further demonstrate whether the drug offers a treatment benefit and whether the drug is safe.
<b>Placebo-Controlled Trial</b>	A trial where a new treatment is compared to an inactive substance (placebo).
<b>Primary Endpoint</b>	The main, pre-determined objective of the trial to establish the effectiveness and/or safety features of a drug in order to support approval by the FDA.
<b>Pro Re Nata ("PRN")</b>	Latin term for "as needed" or "as the situation arises."
<b>Rescue Injections</b>	Lucentis injections required for Wet AMD patients to maintain vision.
<b>Reverse Merger</b>	When a private company becomes publicly traded without utilizing an initial public offering by acquiring the shares of a shell company that is publicly traded.
<b>Secondary Endpoint</b>	Measures selected to demonstrate additional effects or benefits of a drug.
<b>Squalamine</b>	An agent derived from the liver of the dogfish shark that was developed and tested by Genaera and later Ohr.
<b>Treatment Arm</b>	Group of patients in a clinical trial that receives the new treatment.



**GLOSSARY**

<b>TERM</b>	<b>MEANING</b>
<b>Trial Protocol</b>	A document that provides the objectives, design, methodology, statistical considerations, and organization of a clinical trial.
<b>Vascular Endothelial Growth Factor (“VEGF”)</b>	Protein that stimulates the growth of new blood vessels in the body.
<b>Visual Acuity</b>	The clearness or sharpness of vision measured at the distance of 20 feet.
<b>Wet Age-Related Macular Degeneration (“Wet AMD”)</b>	A progressive disease affecting the cells in the macula, a portion of the retina, which causes rapid vision loss.

**TABLE OF PERSONS AND ENTITIES**

<b>NAME</b>	<b>DESCRIPTION</b>
<b>Advanced Viral Research, Co.</b>	Pharmaceutical company that was run by Shalom Hirschman
<b>Backenroth, Sam</b>	Ohr's Chief Financial Officer since April 2010
<b>BBM Holdings, Inc.</b>	Entity through which Ohr was created through a reverse merger
<b>Boyer, David</b>	Ophthalmologist who has served as a member of Ohr's Scientific Advisory Board since 2013
<b>Brown, David</b>	Ophthalmologist who served as the head of the steering committee for the MAKO Trial
<b>Corporate Profile LLC</b>	Stock promotor hired by Ohr
<b>Genaera Corporation</b>	Pharmaceutical company that tested Squelamine from 2001 to 2007 and later sold the rights to the compound to Ohr
<b>Greenstein, Ira</b>	Ohr's founder and Chairman from 2007 to May 2017
<b>Heier, Jeffery</b>	Ophthalmologist based in Boston who served as a member of Ohr's Scientific Advisory Board since 2013
<b>Hirschman, Orin</b>	Founder and director of Ohr
<b>Hirschman, Shalom</b>	Ohr's founder and Chief Scientific Advisor from 2009 to December 2013
<b>Kaiser, Peter</b>	Ohr's Head of Product Development (Senior Vice President) since May 2014
<b>Limpert, Andrew</b>	Ohr's Chief Executive Officer from 2009 to April 2010
<b>Prime Resources, Inc.</b>	Entity that preceded Ohr
<b>SKS Ocular LLC</b>	Entity acquired by Ohr in May 2014
<b>Slakter, Jason</b>	Ohr's Chief Medical Officer from May 2014 to August 2015 and Chief Executive Officer starting in August 2015
<b>Stoller, Glenn</b>	Ohr's Chief Scientific Officer starting in May 2014
<b>Taraporewala, Irach</b>	Ohr's Chief Executive Officer from April 2010 to August 2015
<b>Vista Partners LLC</b>	Stock promotor hired by Ohr

**CHRONOLOGY**

<b>DATE</b>	<b>EVENT</b>
<b>March 1, 2006</b>	Genaera announces the interim results for its phase II trial of Squalamine. ¶38.
<b>January 3, 2007</b>	Genaera announces that it will stop testing Squalamine because there is no attractive or pragmatic option for the registration and commercialization of Squalamine for the treatment of wet AMD. ¶40.
<b>June 2009</b>	Genaera files for bankruptcy. ¶41.
<b>August 4, 2009</b>	Ohr Pharmaceutical, Inc. is founded through a reverse merger with BBM Holdings. ¶30
<b>August 21, 2009</b>	Ohr acquires the rights to Squalamine and Trodusquemine from Genaera for \$200,000. ¶41.
<b>April 12, 2010</b>	Irach Taraporewala and Sam Backenroth are appointed as CEO and CFO, respectively. ¶42.
<b>October 2010</b>	Corporate Profile begins promoting Ohr and Squalamine. ¶43.
<b>September 2012</b>	Ohr initiates the IMPACT Trial. ¶45.
<b>January 9, 2013</b>	Ohr files a letter from its auditor expressing doubt that the Company will be able to continue as a going concern. ¶47.
<b>June 12, 2013</b>	Ohr common stock is registered on the NASDAQ. ¶48.
<b>April 8, 2014</b>	Class Period begins. ¶51.
<b>April 8, 2014</b>	Ohr commences its first stock offering for 1.8 million shares of common stock at \$10.00 per share, raising approximately \$18 million.
<b>April 8, 2014</b>	Defendants make false and/or misleading statements to the market regarding the previous trials for Squalamine conduct by Genaera. ¶52.
<b>May 5, 2014</b>	Ohr acquires SKS Ocular LLC and appoints its principals: Jason Slakter as CMO, Glen Stoller as CSO, and Peter Kaiser as Head of Product Development. ¶53.
<b>June 24, 2014</b>	Ohr touts the Interim Results from the IMPACT Trial. ¶54.
<b>June 24, 2014</b>	Defendants begin making false and/or misleading statements to the market regarding the Interim Results, stating, <i>inter alia</i> , that “the visual acuity

## CHRONOLOGY

DATE	EVENT
	gains for the placebo eye drop arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment.” ¶58.
<b>June 26, 2014</b>	Vista Partners publishes a so called “research report” and press release about the IMPACT Trial’s Interim Results, but does not disclose in the press release that Vista was paid by Ohr. As a result, Ohr’s stock price increases 60% in two days, from a low of \$6.86 to a high of \$10.97. ¶61.
<b>February 9, 2015</b>	Ohr conducts its second offering of common stock during the Class Period, raising approximately \$25 million. ¶62.
<b>March 27, 2015</b>	Ohr touts the IMPACT Trial’s final results for patients with classic-containing lesions, a/k/a the Classic Lesions Results. ¶63.
<b>March 27, 2015</b>	Defendants begin making false and/or misleading statements regarding the Classic Lesions Results, stating, <i>inter alia</i> , that “[t]here was a clear and clinically meaningful benefit in patients whose lesions contained some classic CNV.” ¶64.
<b>May 11, 2015</b>	Ohr touts the IMPACT Trial’s final results for patients with occult lesions smaller than 10mm <sup>2</sup> , a/k/a the Occult Lesions Results, stating, <i>inter alia</i> , that “[A] post hoc analysis of 94 of the 128 patients who completed the nine months of the trial who had an area of occult CNV at baseline of a less than 10 square millimeters or about four disk areas. As you will see a significant difference in outcome between the two treatment groups is noted. This includes patients with both classic containing as well as occult-only lesions. With OHR-102 combination therapy, there is a gainable 11 letters at month nine versus a 5.7 letter gain in the Lucentis monotherapy group, a difference of 5.3 letters.” ¶68.
<b>August 7, 2015</b>	Jason Slakter is appointed as CEO of Ohr. ¶67.
<b>March 29, 2016</b>	Ohr initiates the phase III MAKO Trial for Squalamine. ¶70.
<b>December 7, 2016</b>	Ohr conducts its third offering of common stock, raising approximately \$6.9 million. ¶71.
<b>April 5, 2017</b>	Ohr conducts its fourth offering of common stock, raising approximately \$12.7 million. ¶72.
<b>December 15, 2017</b>	Ohr files a letter from its auditor in its 2017 10-K expressing doubt that the Company will be able to continue as a going concern. ¶72.
<b>January 4, 2018</b>	Class Period ends. ¶132.

**CHRONOLOGY**

DATE	EVENT
<b>January 5, 2018</b>	Ohr announces the results for the MAKO Trial before the market opens. ¶75.
<b>January 5, 2018</b>	Ohr's stock price drops \$1.64 per share from the prior day's close at \$2.02 per share, to close at \$0.38 per share, a drop of more than 81%. ¶75.

The allegations in this Amended Class Action Complaint are based on the personal knowledge of Lead Plaintiffs George Lehmann and Insured Benefits Plans, Inc. (together “**Lead Plaintiffs**”) as to Lead Plaintiffs’ own acts, and are based upon information and belief as to all other matters alleged herein.<sup>1</sup> Lead Plaintiffs’ information and belief is based upon the investigation by Lead Plaintiffs’ counsel into the facts and circumstances alleged herein, including: (i) review and analysis of those public filings referenced herein that Ohr Pharmaceutical, Inc. (“**Ohr**” or the “**Company**”) made with the United States Securities and Exchange Commission (“**SEC**”); (ii) review and analysis of those press releases, analyst reports, public statements, news articles, and other publications referenced herein disseminated by or concerning Ohr and the other Individual Defendants named herein (together with Ohr, “**Defendants**”); (iii) review and analysis of those Company conference calls, press conferences, and related statements and materials referenced herein; and (iv) review and analysis of those other documents referenced herein. Many additional facts supporting the allegations are known only to Defendants and/or are within their exclusive custody or control. Lead Plaintiffs believe that additional evidentiary support for the allegations will emerge after a reasonable opportunity to conduct discovery.

### NATURE AND SUMMARY OF THE ACTION

1. Subject to certain exclusions detailed herein, this is a federal securities class action on behalf of a class consisting of all persons and entities who purchased or otherwise acquired Ohr common stock in the United States or on the NASDAQ Capital Market from April 8, 2014 through January 4, 2018, both dates inclusive (the “**Class Period**”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies

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<sup>1</sup> All emphases are added to quotations and all internal citations and internal quotations are omitted unless otherwise noted.

under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “**Exchange Act**”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top executives.

2. Ohr did not start out as a pharmaceutical development company. Rather, Ohr was formed through a reverse merger with a company that spent its infancy as a fledgling broadband services company operating under a different name. In 2009, Ohr shifted focus and purchased from the then-bankrupt Genaera Corporation (“**Genaera**”) the rights to Squalamine (f/k/a **EVIZON**) and Trodusquemine, two compounds derived from the liver of the dogfish shark, for just \$200,000.

3. For more than seven years prior thereto, Genaera had attempted to develop Squalamine into a treatment for patients with Wet Age-Related Macular Degeneration (“**Wet AMD**”). Wet AMD is the leading cause of blindness in the elderly and is an eye disorder that damages the center of the retina, thereby causing vision loss. Genaera ran a series of clinical trials in patients with the disease, but all of its trials of Squalamine produced disappointing results. Consequently, in 2007, Genaera decided to stop testing Squalamine because Genaera’s trials showed that there was no attractive or pragmatic option for the registration and commercialization of Squalamine for the treatment of Wet AMD. Notably, six months prior, Lucentis<sup>®</sup> a/k/a ranibizumab (“**Lucentis**”) became the first FDA-approved therapy to treat Wet AMD. Lucentis is the current standard of care for Wet AMD patients and is administered through intravitreal injections into the eye every 4 to 8 weeks, as the drug’s efficacy degrades over time.

4. After Ohr purchased Squalamine from Genaera, Ohr repackaged it in 2011 into an eye-drop (it was previously administered intravenously) to be tested in patients with Wet AMD. To spearhead the testing of Squalamine, Ohr hired two officers with limited experience in ophthalmology. That is, in April 2010, Irach Taraporewala joined Ohr as CEO, and Sam

Backenroth joined Ohr as CFO. This was Taraporewala's fourth new position in five years and Backenroth was a 26-year-old with two years of investment banking experience at Benchmark Company, LLC. Neither Taraporewala nor Backenroth had a medical degree. For the following four years, they served as Ohr's sole officers.

5. In 2012, Ohr began testing Squalamine in humans in Ohr's "**IMPACT Trial**," a/k/a OHR-002, a phase II clinical trial of Squalamine in patients with Wet AMD.<sup>2</sup> The IMPACT Trial was designed to enroll 142 patients in two arms. In the treatment arm,<sup>3</sup> patients received Squalamine eye drops twice a day in combination with injections of Lucentis (the "**Squalamine Arm**") as needed to maintain vision. In the control arm,<sup>4</sup> patients received placebo eye drops twice a day in combination with injections of Lucentis (the "**Lucentis Monotherapy Arm**") as needed. Monotherapy is the use of a single drug to treat a disease or condition. Definition of Cancer Terms, National Cancer Institute, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/monotherapy> (last visited July 20, 2018). The primary endpoint of the trial was the reduction in Lucentis injections after

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<sup>2</sup> In order to secure approval by the FDA, a new drug must typically succeed in three phases of clinical trials. Phase I trials are usually the first trials to be conducted on people and are designed to determine the highest dosing amount for the drug that is safe and does not cause serious side effects. *See* The Drug Development Process, FDA (Jan. 4, 2018), <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm>. If the phase I trial shows that the drug is safe, phase II trials are conducted in several hundred patients to determine whether the drug is effective and how long the effect lasts in patients. *See id.* If the drug is shown to be effective in the phase II trials, then phase III trials are conducted in a broader number of patients to further demonstrate whether the drug offers a treatment benefit to patients and whether the drug is safe for the target population. *See id.*

<sup>3</sup> This refers to the group of patients in a clinical trial that receives the new treatment.

<sup>4</sup> This refers to the group of patients in a clinical trial who do not receive the new treatment under study in order to compare the treatment to receiving no treatment or the standard of care.



nine months to maintain vision; and the secondary endpoint was improvement in vision—also known as best corrected visual acuity (“**BCVA**”)—as measured by the Early Treatment Diabetic Retinopathy Study (“**ETDRS**”) scale. This scale is the standard eye chart (“**Standard Eye Chart**”).

6. The results for the first half of the patients enrolled in the IMPACT Trial were due to be announced in mid-2014. Facing the risk of continuing as a going concern (as determined by Ohr’s auditors), Ohr began a promotional campaign to tout Squalamine. In certain presentations and SEC filings, Ohr misleadingly represented that the prior phase II trials conducted by Genaera for Squalamine were successful, stating that “*the administration of Squalamine produced beneficial effects and significant improvement in best corrected visual acuity[.]*” Ohr failed to mention, however, that Genaera itself had determined that the efficacy results from these trials were weak and did not justify further testing of Squalamine. Furthermore, the visual acuity results for the Genaera trials of Squalamine were far worse than the visual acuity results from the trials that Genentech, Inc. (“**Genentech**”) used to gain FDA-approval of Lucentis. In any event, after sufficiently driving up Ohr’s stock price with misrepresentations about Squalamine, on April 8, 2014, Ohr initiated its first of four stock offerings, raising approximately \$18 million. The Class Period in this action begins on the date of this offering when Ohr filed a prospectus supplement with the SEC in support of this offering and therein made misleading statements regarding the success of the previous trials conducted by Genaera.

7. Additionally, during the Class Period, Ohr touted three data points from the IMPACT Trial: (1) the Trial’s interim visual acuity results (the “**Interim Results**”); (2) the final

visual acuity results for Wet AMD patients with classic-containing lesions<sup>5</sup> (the “**Classic Lesions Results**”); and (3) the final visual acuity results for Wet AMD patients with occult lesions<sup>6</sup> less than 10mm<sup>2</sup> (the “**Occult Lesions Results**”).

8. First, on June 24, 2014, Ohr announced visual acuity results for the first half of the patients enrolled in the IMPACT Trial, *i.e.*, the Interim Results. Ohr reported that patients in the Squalamine Arm had a mean vision improvement of **10.4 letters** on the Standard Eye Chart whereas patients in the Lucentis Monotherapy Arm had a mean improvement of **6.3 letters**, a relative difference of **4.1 letters**. Ohr hyped these results and proclaimed that the visual acuity numbers were the “**most clinically relevant measure**” for determining Squalamine’s efficacy in treating Wet AMD.

9. To further tout these results, Ohr hired a stock pumper named Vista Partners LLC (“**Vista**”) to issue a press release and “research report” on June 26, 2014 lauding the Interim Results. In the press release and report, Vista raised its price target on Ohr’s stock from \$14 to \$31 per share, at a time when Ohr’s stock was trading at \$7.31. Vista’s press release and price target were picked up by other investing websites and resulted in **Ohr’s stock price soaring 60% in two days, from a low of \$6.86 per share to a high of \$10.97**. Notably, the press release omitted that Ohr hired Vista, in violation of Section 17(b) of the Securities Act of 1933, 15 U.S.C. § 77q(b).

10. For the remainder of 2014, Ohr continued to make misleading statements regarding the Interim Results, touting the data as “**truly remarkable**” and showing a “**robust and rapid response**.” Ohr also assured investors that the trial’s benchmark (namely the results from

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<sup>5</sup> A type of Wet AMD lesions that has a demarcated border.

<sup>6</sup> A type of Wet AMD lesion that has a diffuse, poorly-defined border.

the control arm) had not underperformed as “*the visual acuity gains for the Lucentis Monotherapy Arm were consistent with those observed in previous clinical studies using Lucentis*[.]” These statements were false and misleading because in the prior trials of Lucentis, patients gained a mean of **7.94 letters** – 1.64 letters higher than the Lucentis Monotherapy Arm’s Interim Results. Indeed, if patients in the Lucentis Monotherapy Arm of the Interim Results had performed consistently with prior trials, the relative difference in visual acuity between the two arms of the IMPACT Trial’s Interim Results would shrink from **4.1 letters** to **2.46 letters**. This smaller relative difference would not be clinically meaningful, as a Wet AMD treatment must improve vision by **at least 4 letters** to be considered clinically meaningful according to Dr. David Boyer, a member of Ohr’s own Scientific Advisory Board. Rather than truthfully disclose and explain this shortcoming in the Interim Results, Ohr conducted a second offering of common stock on February 6, 2015, raising total proceeds of approximately \$25 million.

11. Second, on March 27, 2015, Ohr touted the Classic Lesions Results, which were the final visual acuity results for 70 patients in the IMPACT Trial who had “classic-containing” Wet AMD lesions. The patients in the Squalamine Arm showed a mean improvement in visual acuity of **10.5 letters** whereas the Lucentis Monotherapy Arm showed a mean improvement in visual acuity of **5.4 letters**, a relative difference of **5.1 letters**.

12. The Company continued to tout the aforementioned visual acuity results as “*clinically meaningful*” and showing “*a clear efficacy signal*.” But when making these statements, the Company failed to disclose that the Lucentis Monotherapy Arm once again materially underperformed in the IMPACT Trial compared to the results from past Lucentis trials—thereby lowering the benchmark by which the final results of the IMPACT Trial’s Squalamine Arm were being compared, and thereby creating a misleading impression of the Squalamine Arm’s performance. In other words, if the Lucentis Monotherapy Arm of the

Classic Lesions Results had performed consistently with past Lucentis trials and achieved a visual acuity gain of 7.94 letters, the difference between the Squalamine Arm and the Lucentis Monotherapy Arm shrinks from *5.1 letters* to *2.56 letters, a difference which is not clinically meaningful.*

13. Third, on May 11, 2015, Ohr touted a third data point, namely the Occult Lesions Results, which were the results for patients with occult Wet AMD lesions that were smaller than 10 mm<sup>2</sup> in size. These results showed that the mean visual acuity for patients in the Squalamine Arm improved by *11 letters* whereas the mean visual acuity for patients in the Lucentis Monotherapy Arm improved by *5.7 letters*, a relative difference of *5.3 letters*. Defendants again failed to disclose that, had the Lucentis Monotherapy Arm not materially underperformed in comparison to historical trials, the results *would not have been clinically meaningful*. Indeed, had patients in the Lucentis Monotherapy Arm performed consistently with prior Lucentis trials and achieved a gain of 7.94 letters, the relative difference between the two arms would shrink from *5.3 letters* to *3.06 letters, again not a clinically meaningful difference.*

14. After touting these results, Ohr announced on March 29, 2016 that the Company was initiating its phase III MAKO trial (the “**MAKO Trial**”) for Squalamine in patients with Wet AMD. The MAKO Trial was designed to have two arms like the IMPACT Trial, but was to enroll 650 patients and span two years. Riding high on the enthusiasm the Defendants generated for the MAKO Trial, the Company conducted a third offering of common stock, earning total proceeds of approximately \$6.9 million.

15. After Ohr spent two years touting the various results from the IMPACT Trial, on April 5, 2017, Ohr initiated its fourth offering of common stock, raising approximately \$12.7 million in proceeds, which when combined with the proceeds from Ohr’s prior three offerings raised a total of \$62 million.

16. Then, on January 5, 2018, before the market opened, Ohr announced the much-awaited results from the MAKO Trial. The trial was an utter disaster as patients in the Squalamine Arm performed worse than the Lucentis Monotherapy Arm, achieving a mean gain of 8.33 letters versus a mean gain of 10.58 letters in the Lucentis Monotherapy Arm. On this news, Ohr's stock price plummeted \$1.64 per share from \$2.02 per share at the close of the day's prior trading to close at \$0.38 per share on January 5, 2018, a drop of approximately **81.2%**.

17. Unbeknownst to investors during the Class Period, the true facts, which were known and/or recklessly disregarded by Ohr and its officers, directors, and executives, but which were concealed from the investing public were that:

- (a) Genaera's prior clinical trials of Squalamine did not demonstrate that Squalamine had a favorable biological effect or improved visual acuity outcomes;
- (b) Genaera terminated its development of Squalamine for the treatment of Wet AMD because Genaera concluded, based on the data available from its trials, that Squalamine was unlikely to produce vision improvement with the speed or frequency necessary to compete with Lucentis and that there was "no attractive or pragmatic option for the registration and commercialization of Evizon for the treatment of wet AMD";
- (c) Genaera's phase II trials for Squalamine resulted in vision gains far inferior to those produced by Lucentis. In Genaera's Study 209, only 5% of subjects treated with 40 mg of Squalamine gained vision and only 4% of subjects treated with 20 mg of Squalamine gained vision, whereas, in the trials used to support FDA approval of Lucentis, 40% of patients treated with Lucentis gained vision; and
- (d) The 6.3-letter mean visual acuity gain observed in the Lucentis Monotherapy Arm of the IMPACT Trial's Interim Results underperformed the mean 7.94-letter-gain

observed in prior studies of Lucentis monotherapy treatment;

- (e) Had the Lucentis Monotherapy Arm in the IMPACT Trial's Interim Results performed as well as the Lucentis treatment arms in prior studies of Lucentis, the relative improvement of the Squalamine Arm compared to the Lucentis Monotherapy Arm would only have been a negligible 2.46-letter-improvement—a difference that is not clinically meaningful;
- (f) Had the Lucentis Monotherapy Arm in the IMPACT Trial's Interim Results performed as well as the Lucentis treatment arms in prior studies of Lucentis, the additional relative benefit for the Squalamine Arm compared to the Lucentis Monotherapy Arm would only have been 31% (as opposed to the 65% asserted by Ohr);
- (g) As a result of (d), (e), and (f), the visual acuity results observed in the Squalamine Arm of the IMPACT Trial's Interim Results were neither “truly remarkable” (§82) nor did they show “dramatic vision gains” (§83), “substantial gains” (§88), a “positive benefit in clinically relevant visual function” (§§ 82, 85-87) or “marked improvements” (§90).
- (h) The visual acuity gains observed in the Lucentis Monotherapy Arms of the Classic Lesions Results (5.4 letters) and the Occult Lesions Results (5.7 letters) underperformed the mean 7.94-letter-gain observed in prior studies of Lucentis monotherapy treatment;
- (i) Had the Lucentis Monotherapy Arms of the Classic Lesions Results and the Occult Lesions Results performed as well as the Lucentis monotherapy treatment arms in prior studies of Lucentis, the relative improvement of the Squalamine Arms compared to the Lucentis Monotherapy Arms would have only been a

negligible 2.56-letter-improvement for the Classic Lesions Results and a 3.06-letter-improvement for the Occult Lesions Results—neither of which is a clinically meaningful difference.

### **JURISDICTION AND VENUE**

18. This action arises under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b), 78t(a)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

19. This Court has jurisdiction over the action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

20. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b), as Ohr maintains its principal place of business in this District and certain of the acts and conduct complained of herein, including dissemination or omission of materially false and misleading information to the investing public, occurred in this District.

21. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, the Internet, and the facilities of the national securities markets.

### **THE PARTIES**

#### **A. Lead Plaintiffs**

22. Lead Plaintiffs George Lehmann and Insured Benefits Plans, Inc. purchased common stock at artificially inflated prices during the Class Period and were damaged thereby when the truth was revealed. Lead Plaintiffs purchased Ohr common stock during the Class Period as set forth in ECF No. 15-2 and were damaged thereby.

**B. Defendants**

23. Defendant Ohr is incorporated in Delaware and has its principal executive offices located at 800 Third Avenue, 11th Floor, New York, NY 10022. Ohr is presently a pharmaceutical company focused on the development of novel therapies and delivery technologies for the treatment of ocular disease. During the Class Period, Ohr's stock traded on the NASDAQ Capital Market exchange under the ticker symbol "OHRP."

24. Defendant Irach Taraporewala ("**Taraporewala**") served as Ohr's Chief Executive Officer ("**CEO**") from April 12, 2010 to August 6, 2015.

25. Defendant Jason S. Slakter, M.D. ("**Slakter**") served as Ohr's Chief Medical Officer ("**CMO**") from May 2014 to August 6, 2015, and he served as Ohr's CEO from August 7, 2015 to the present. Slakter has served as a Director on Ohr's Board of Directors since January 2015.

26. Defendant Sam Backenroth ("**Backenroth**") served as Ohr's Chief Financial Officer ("**CFO**") and Vice President of Business Development from April 12, 2010 to the present.

27. Defendants Taraporewala, Slakter, and Backenroth are referred to herein as the "**Individual Defendants**," and together with Ohr they are referred to herein as "**Defendants**."

**FACTUAL BACKGROUND**

**A. Ohr Began As A Shell Corporation**

28. Ohr began as a shell corporation founded by Shalom Hirschman, M.D. ("**Dr. Hirschman**") and Orin Hirschman. Tellingly, the corporate shell behind Ohr began as Prime Resources, Inc., a group insurance brokerage that offered investment and pension consulting services. *See* Ohr Pharmaceutical, Inc., Annual Report (Form 10-K), 2 (Jan. 13, 2012). In April



2006, Prime Resources sold off its assets and began to look for reorganization partners. *See* Ohr Pharmaceutical, Inc., Annual Report (Form 10-K), 4 (Jan. 13, 2009).<sup>7</sup>

29. In March 2007, Prime Resources found its partners and changed its name to “BBM Holdings, Inc.” (“BBM”), beginning the process of executing the Company’s first attempt at a reverse merger<sup>8</sup> into Broadband Maritime, Inc., a company providing broadband internet service and international telephone service for the maritime industry. *See* Ohr Pharmaceutical, Inc., Annual Report (Form 10-K), 1 (Jan. 13, 2012). However, this venture failed two months later on June 5, 2007 and the company ceased operations. *Id.*

30. On November 12, 2008, Ohr initiated its second – and ultimately successful – attempt at a reverse merger by entering into an agreement with Dr. Hirschman to act as a consultant to help lead the company in a “creative new direction.” *See* Ohr Pharmaceutical, Inc., Annual Report (Form 10-K), 8 (Jan. 13, 2009).<sup>9</sup> On August 4, 2009, the reverse merger process

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<sup>7</sup> During this time, Andrew Limpert served as the CEO of Prime Resources. *Id.* at 8. Limpert has a history of engaging in questionable business practices. For example, on July 11, 2012, Limpert was **sanctioned by the SEC** for multiple Securities Act, Exchange Act, and Investment Adviser Act violations and, *inter alia*, was ordered to pay a \$112,956.78 penalty. This sanctionable conduct, while not related to Ohr, occurred during his tenure as CEO and president of Ohr. *See In the Matter of Belsen Getty, LLC, Terry M. Deru, & Andrew W. Limpert, Respondents.*, Release No. 3430, 2012 WL 2836956 (July 11, 2012).

<sup>8</sup> A reverse merger occurs when a private company becomes public without utilizing an initial public offering (“IPO”) by acquiring all shares of the shell company’s stock. *See* Office of Investor Educ. & Advocacy, *Investor Bulletin: Reverse Mergers*, Securities and Exchange Commission, 1, *available at* <https://www.sec.gov/investor/alerts/reversemergers.pdf>. In effect, this transforms the private acquirer into a public company which gives it access to a broader pool of investors. *Id.* According to the SEC, “[a] reverse merger often is perceived to be a quicker and cheaper method of ‘going public’ than an initial public offering . . . [W]hile the public shell company is required to report the reverse merger in a Form 8-K filing with the SEC, there are no registration requirements under the Securities Act of 1933 as there would be for an IPO.” *Id.*

<sup>9</sup> Dr. Hirschman previously served as the CEO and Chief Scientific Officer (“CSO”) of Advanced Viral Research Co., another failed pharmaceutical company. *See* Advanced Viral Research Co., Press Release (Form 8-K), 2 (Jan. 23, 2009). While at Advanced Viral Research Co., Hirschman developed a cancer drug known as AVR118. *See* Advanced Viral Research Co.,

concluded when BBM completed a reincorporation merger and officially became Ohr Pharmaceutical, Inc., a pharmaceutical development company. *See* Ohr Pharmaceutical, Inc., Annual Report (Form 10-K), 1 (Jan. 8, 2010).

## **B. Prior Wet AMD Trials Of Squalamine Failed**

31. While Orin Hirschman was running BBM, Squalamine (the drug that would become Ohr's principal product) was being developed and tested by Genaera Corporation ("Genaera"). Genaera began developing Squalamine for the treatment of Wet AMD in 2001 and gave the product the trade name "EVIZON." *See* Genaera Corporation, Press Release (Form 8-K, Ex. 99.1) (Feb. 28, 2005).

### **1. Wet AMD**

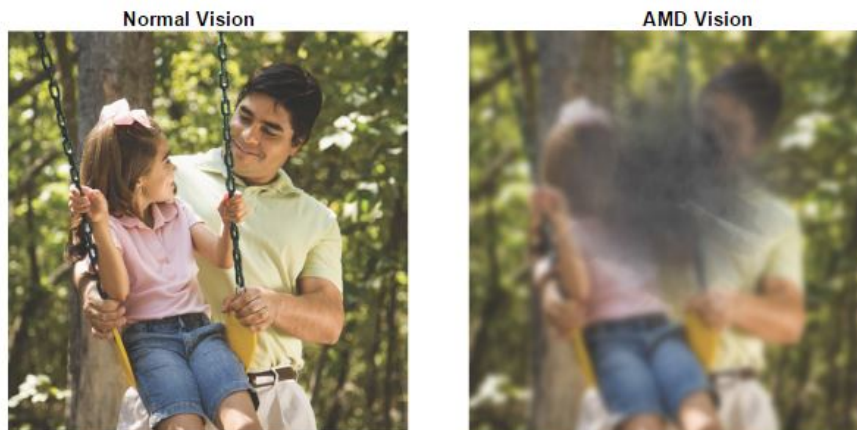
32. Wet AMD is a disease affecting the cells in the macula, which is an area that forms the center of the retina and is the region of the eye responsible for central vision. *See* American Macular Degeneration Foundation, What is Macular Degeneration?, <https://www.macular.org/what-macular-degeneration> (last visited May 24, 2018). Patients with Wet AMD suffer debilitating vision loss and it is the leading cause of blindness. *Id.*

33. Wet AMD occurs when the membrane underlying the retina thickens, then breaks. *See* The Macular Degeneration Partnership, Wet AMD, <https://www.amd.org/what-is-macular-degeneration/wet-amd/> (last visited May 24, 2018). The body responds by growing new,

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Annual Report (Form 10-K), 1, 31 (Mar. 12, 2007). After the company shut down on January 23, 2009, YA Global Investments, L.P., a secured creditor, took ownership of AVR118. *Id.* Less than two months later, on March 19, 2009, Prime Resources, Inc. purchased the rights associated with AVR118 from YA Global Investments, L.P. *See* Ohr Pharmaceutical, Inc., Annual Report (Form 10-K), 1 (Dec. 27, 2013); *see also* Ohr Pharmaceutical, Inc. Annual Report (Form 10-K/A) (Ex. 10.6) (Form of Securities Purchase Agreement), 18, (Apr. 2, 2009). The cash portion of the purchase price was financed by short-term loans from an affiliate of Orin Hirschman. *Id.* 1, 6. In effect, the Hirschmans bankrupted one publicly traded company and then used another publicly traded company to buy the bankrupted company's only asset at a reduced price.

abnormal blood vessels in a process known as choroidal neovascularization (“CNV”). *See id.*; *see also* American Macular Degeneration Foundation, Wet Macular Degeneration (AMD), <https://www.macular.org/wet-amd> (last visited May 24, 2018). In Wet AMD patients, areas of abnormal blood vessels and altered tissue are referred to as “lesions.” A depiction of the type of vision loss experienced by patients with Wet AMD is set forth below:



34. In the years since Genaera began testing Squalamine, a number of therapies have been approved by the FDA to treat Wet AMD. *See id.* The most common FDA-approved treatments are as follows: (1) Lucentis, marketed by Genentech and Novartis AG; (2) EYLEA<sup>®</sup>, marketed by Regeneron Pharmaceuticals, Inc.; and (3) Avastin<sup>®</sup>, marketed by Genentech. *See id.* These treatments are administered through intravitreal injections. These therapies do not cure the disease because the biologic agents decay over time, causing only temporary vision improvement/maintenance. As a result, these drugs require injections every 4 to 8 weeks to maintain stable vision. *See* C. Claiborne Ray, Fighting Macular Degeneration, N.Y. Times, Mar. 22, 2016, D4.

35. Two key measures physicians use to monitor a patient’s disease progression are CNV lesion size and visual acuity.

36. When a patient has Wet AMD, a lesion appears on the surface area on the retina where the CNV has occurred. *See* [www.amdbook.org](http://www.amdbook.org), <http://amdbook.org/content/classic-cnv>. There are two different types of lesions based on appearance – classic and occult. *See* Ursula Schmidt-Erfurth et al., *Three Dimensional Angiography Classic and Occult Lesion Types in Neovascularization*, 48 Investigative Ophthalmology & Vision Science 1751 (2007). Classic lesions have a demarcated border, are more aggressive, and cause early and substantial vision loss. *Id.* Occult lesions have a diffuse, poorly defined border and often present with long-term maintenance of vision until the retina becomes damaged. *Id.* The lesion types can form separately or in combination. *See* Joachim Wachtlin, *Classic Choroidal Neovascularization*, in *Atlas of Fundus Angiography* (Georg Thieme Verlag ed. 2006). CNV lesions are measured by square millimeters. A lesion 2.54 to 5mm<sup>2</sup> in size is considered small; 5 to 7.62mm<sup>2</sup> is considered medium; and 7.62 to 12.7mm<sup>2</sup> is considered large. *See* Slingshots Insights Telephone Interview with Dr. David Boyer, Ophthalmologist (Dec. 29, 2015) (transcript available through Slingshot Insights, Inc.)

37. Visual acuity is the clearness or sharpness of vision measured at a distance of 20 feet. *See* American Optometric Association, *Visual Acuity: What is 20/20 Vision?*, <http://www.aoa.org/patients-and-public/eye-and-vision-problems/glossary-of-eye-and-vision-conditions/visual-acuity?sso=y> (last visited June 19, 2018). The Standard Eye Chart is characterized by lines of five letters each decreasing in size, which is used to measure visual acuity. *See* Jerry Isaacson, *Ohr Pharmaceutical, Inc. Initiation Report*, LifeSci Capital, 11 (July 18, 2015). In Wet AMD clinical trials, the number of letters read at baseline before treatment is applied, relative to the number of letters read at follow up evaluations after treatment is applied, determines whether visual acuity has increased, stabilized, or decreased over time. An example of the Standard Eye Chart scale is included below:



## 2. Genaera's Clinical Trials of Squalamine in Wet AMD Failed

38. From 2003 to 2007, Genaera conducted various clinical trials of Squalamine, an agent derived from the liver of the dogfish shark, in patients with Wet AMD. *See* Genaera Corporation, Annual Report (Form 10-K), 1-2, (Mar. 7, 2006). “**Study 209**” was a phase II clinical trial designed to assess the safety of two doses of Squalamine (40 mg and 20 mg) and Squalamine’s potential effect on visual acuity over a two-year period. *Id.* In Study 209, intravenous treatment of Squalamine was administered weekly for the first four weeks and monthly thereafter. *See* Genaera Corporation, Press Release (Form 8-K, Ex. 99.1) (Mar. 1, 2006). Interim data of 108 subjects after six months showed lackluster results. In the 40 mg group, only 5% of subjects gained vision (defined as a gain of 15 letters or more in visual acuity) and 79% of subjects maintained vision (defined as a loss of less than 15 letters in visual acuity). *Id.* In the 20 mg group, 4% of subjects gained vision and 69% maintained vision. *Id.* In the control group, 0% gained vision and 71% maintained vision. *Id.* Genaera never disclosed the final data from this study. Genaera soon began enrolling another phase II clinical trial, “**Study 212**,” to evaluate whether higher doses of Squalamine would produce stronger results. *See* Genaera Corporation, Annual Report (Form 10-K), 1-2, (Mar. 7, 2006).

39. Around this time, on June 20, 2006, the FDA approved Lucentis as the first treatment for Wet AMD. *See* Genentech, Quarterly Report (Form 10-Q), 30, (Aug. 3, 2006). Unlike Squalamine, which was still only being tested in small-scale phase II studies, FDA approval of Lucentis was based on data from two large phase III clinical trials—MARINA and ANCHOR. *Id.* ***The visual acuity results from these trials were far superior to the Study 209 results.*** In these studies, ***40% of patients treated with Lucentis improved vision*** (defined as the gain of 15 letters or more in visual acuity) at one year and ***95% of patients maintained vision*** (defined as the loss of less than 15 letters in visual acuity at one year). *See* Genentech, *FDA Approves LUCENTIS for the Treatment of Wet Age-Related Macular Degeneration* (June 30, 2006), <https://www.gene.com/media/press-releases/9787/2006-06-30/fda-approves-lucentis-for-the-treatment->. Compared to Genaera's Study 209, where only 5% of subjects improved vision and 79% maintained vision, ***Lucentis performed eight times better than Squalamine.*** *See* Genaera Co., Press Release (Form 8-K, Ex. 99.1) (Mar. 2, 2006).

40. Given the underwhelming results of Study 209, it was clear that continued testing of Squalamine in Study 212 would be a lost cause; thus, Genaera subsequently announced that it was terminating its Squalamine (then known as EVIZON) clinical program, explaining:

***[P]reliminary information from investigators on patients enrolled to date in Study 212 suggests that EVIZON is unlikely to produce vision improvement with the speed or frequency necessary to compete with recently introduced treatments. Faced with this discouraging information, as well as evolving FDA guidance on clinical endpoints, we have concluded that there is no attractive or pragmatic option for the registration and commercialization of EVIZON for the treatment of wet AMD. As a result, we cannot justify continuing to expend our limited resources on the clinical development of EVIZON.***

*See* Genaera Corporation, Press Release (Ex. 99.1) (Jan. 3, 2007). Genaera's CSO, Henry Wolfe, confirmed that Genaera demonstrated that ***Squalamine had no clinical activity in Wet AMD*** when he was the CSO at Genaera.

### C. Ohr Acquires And Develops Squalamine

41. In June 2009, Genaera filed for bankruptcy and began liquidating its assets. *See* Genaera Corporation, Current Report (Form 8-K, Ex. 99.2) (June 12, 2009). As part of that process, on August 21, 2009, Ohr entered into an Asset Purchase Agreement with the Genaera Liquidating Trust to purchase the rights to Squalamine and another pharmaceutical compound called Trodusquemine. *See* Ohr Pharmaceutical, Inc., Press Release, (Form 8-K) (Aug. 26, 2009); *see also* Asset Purchase Agreement (Ex. 10.1) (Aug. 26, 2009). Ohr paid ***only \$200,000*** for both compounds. *Id.* As part of the sale, Ohr acquired all “trade secrets, know-how . . . , processes and techniques, and research and development information, ideas, [and] technical data” for Squalamine and Genaera’s “records of the development of Squalamine and related analog compounds . . . including lab notebooks, FDA filings and correspondence, research reports, research and clinical data, manufacturing and production records, and patent correspondence.” *Id.* at 3, 6.

42. On April 12, 2010, Ohr announced that Irach Taraporewala was replacing Limpert as CEO. *See* Ohr Pharmaceutical, Inc. Press Release (Ex. 99.1) 1 (Apr. 12, 2010). This was Taraporewala’s fourth new position in five years. *See* Irach Taraporewala, LinkedIn, <https://www.linkedin.com/in/irach-taraporewala/> (last visited May 25, 2018). The same day, Sam Backenroth was named CFO. Only 26 years old and a recent college graduate, Backenroth had no management experience and little financial experience, having only worked in investment banking for two years at Benchmark Company, LLC prior to joining Ohr. *See* Ohr Pharmaceutical, Inc., Press Release (Form 8-K, Ex. 99.1) 1 (Apr. 12, 2010); *see also* Sam Backenroth, LinkedIn, <https://www.linkedin.com/in/sam-backenroth-1369997/> (last visited May 25, 2018). Neither Taraporewala nor Backenroth had a medical degree. Yet, ***for the next four***



*years Taraporewala and Backenroth remained the only two officers on Ohr's management team.*

43. In order to bring attention to Squalamine, Ohr hired stock-pumper, Corporate Profile LLC ("**Corporate Profile**"), a "broadcasting website where fashion meets finance" in which "New York's top on-air talent" pumps select stocks. *See About Corporate Profile.com*, Corporate Profile, <http://www.corporateprofile.com/about/> (last visited May 25, 2018). Corporate Profile produced slick videos made to look like official news stories but which were actually promotional pieces. These videos touted Ohr as a "hot stock pick." *See Introducing a Hot New Stock Pick Ohr Pharmaceuticals [sic] (OHRP)*, Corporate Profile (Oct. 15, 2010), <http://www.corporateprofile.com/2010/10/15/introducing-a-hot-new-stock-pick-ohr-pharmaceuticals-ohrp/>. In three other videos, "today's top entertainment talents" explained that Squalamine had the potential to "*create a monumental shift in the way patients are treated for Wet-AMD.*"<sup>10</sup>

44. On June 21, 2011, Ohr announced that it had repackaged Squalamine for ophthalmic indications from an intravenous infusion to a topical eye drop. *See* Ohr Pharmaceutical, Inc., Press Release (Form 8-K, Ex. 99.1) (June 24, 2011). Without having tested the solution in animals or humans, Dr. Hirschman boldly stated that the "Squalamine eye drop program has the potential to create a monumental shift in the way patients are treated for Wet-AMD[.]" *Id.* Unlike Lucentis, which required frequent eye injections, Taraporewala noted that this was a "very patient-friendly method of treatment." *Id.*

45. In September 2012, Ohr initiated the IMPACT Trial, its first of two Squalamine studies conducted during the Class Period. The study was a phase II clinical trial to evaluate the

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<sup>10</sup> Notably, the videos were removed from Corporate Profile's website after Lead Counsel contacted the company.



efficacy and safety of Squalamine for the treatment of Wet AMD by comparing Squalamine in combination with Lucentis to Lucentis alone (*i.e.*, paired with placebo eye drops). *See* Ohr Pharmaceutical, Inc., Annual Report (Form 10-K), 2, (Jan. 9, 2013); Clinical Trial NCT01678963, Clinicaltrials.gov, <https://clinicaltrials.gov/ct2/show/NCT01678963> (last visited June 17, 2018). It was a randomized, double-blind, placebo-controlled study that enrolled 142 Wet AMD patients at 21 clinical sites in the U.S. Ohr Pharmaceutical, Inc., *Ohr Pharmaceutical Initiates Phase II Trial of Squalamine Eye Drops for the Treatment of Wet Macular Degeneration*, PRNewswire (Sep. 24, 2012). At the beginning of the trial, each patient's visual acuity was measured to establish a vision baseline. Then, the patients were divided into two arms: (1) the Squalamine Arm (*i.e.*, the treatment arm); and (2) the Lucentis Monotherapy Arm (*i.e.*, the placebo control arm). In the Squalamine Arm, patients received an initial dose of Lucentis and thereafter self-administered Squalamine eye drops twice daily with additional injections of Lucentis on an as needed basis a/k/a *pro re nata* ("PRN"), for nine months. David M. Brown, et al., *CNV Lesion Characteristics as a Predictor of Visual Outcome in Wet AMD Patients Receiving Combination Therapy of Intravitreal Anti-VEGF Therapy and Topical Squalamine Lactate Ophthalmic Solution*, 57 IOVS 4419 (2016). In the Lucentis Monotherapy Arm, patients received an initial dose of Lucentis and thereafter self-administered placebo eye drops twice daily with additional injections of Lucentis PRN, for nine months. *Id.*

46. The trial protocol included an interim analysis upon the completion of the treatment period in 50% of the patients. *Id.* The primary endpoint measured in each arm was the mean number of Lucentis rescue injections required for patients to maintain vision over the course of nine months. *See* Clinical Trial NCT01678963, Clinicaltrials.gov,

<https://clinicaltrials.gov/ct2/show/NCT01678963> (last visited May 25, 2018).<sup>11</sup> The secondary endpoints included patients' best corrected visual acuity as measured by the number of letters a patient could read on the Standard Eye Chart and the number of adverse events observed as a measure of safety and tolerability. *Id.*

#### **D. Defendants Misrepresent Squalamine's Clinical Trial Results To Pump Up Ohr's Stock Price**

##### **1. Defendants Tout Squalamine in Order To Raise Money**

47. In 2013, Ohr was desperate for cash. Ohr's annual report filed in January of that year disclosed that there is "substantial doubt about our ability to continue as a going concern." Ohr Pharmaceutical, Inc., Annual Report 7 (Form 10-K) (Jan. 9, 2013). In fact, the Company reported no revenues and suffered losses of over \$5 million for the year. *See* Ohr Pharmaceutical, Inc., 2013 Annual Report (Form 10-K) 18 (Dec. 27, 2013). Therefore, in order to raise desperately needed funding, Ohr engaged in a scheme to pump up its stock price.

48. First, to gain broader access to funding and to present itself as a successful pharmaceutical company, Ohr registered on the NASDAQ. *See* Ohr Pharmaceutical, Inc., Certification by the NASDAQ (Form CERTNAS) (June 12, 2013).

49. Then, to raise its NASDAQ-registered stock price, in late 2013, Ohr began a media blitz, presenting at seven separate conferences in seven months. During the presentations, Ohr touted the prospects for Squalamine and boasted that it "*may provide several potential advantages over the FDA approved current standards of care*[,]” even though the IMPACT

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<sup>11</sup> A primary endpoint is the main, pre-determined objective of the trial to establish the effectiveness and/or safety features of a drug in order to support approval of the drug by the FDA. *See* Peter R. Nelson, *Primary and Secondary Endpoints*, Clinical Trials Design in Operative and Non Operative Invasive Procedures (2017). Secondary endpoints may be selected to demonstrate additional effects or benefits of the drug. *Id.*

Trial was not designed to compare the efficacy of Squalamine and Lucentis directly. *See* Ohr Pharmaceutical, Inc., Quarterly Financial Report (Form 8-K) 11-12 (Feb. 14, 2014).

50. Ohr's plan proved successful: its stock price rose from \$6.61 on October 21, 2013 to a high of \$19.65 on March 14, 2014.

51. The Class Period begins on April 8, 2014 when Ohr decided to take advantage of its pumped-up stock price and initiate an offering of common stock.

52. That is, on this day, with only \$3.4 million in cash on hand, Ohr entered into a subscription agreement for a direct offering of common stock in which the Company sold 1.8 million shares at \$10.00 per share, for gross proceeds of approximately \$18 million. Press Release, Ohr Pharmaceutical, Inc., *Ohr Pharmaceutical Announces \$18 Million Registered Direct Offering of Common Stock* (Apr. 8, 2014); Ohr Pharmaceutical, Inc., Quarterly Financial Report (Form 10-Q) (May 13, 2014). Chardan Capital Markets, LLC and Brean Capital, LLC served as the underwriters. *Id.* In the offering documents, Ohr promoted Squalamine by stating that it *had already demonstrated "significant improvement in best corrected visual acuity"* in previous phase II trials. *Id.*

53. Then, shortly after its first major stock offering, Ohr decided to hire management more experienced in ophthalmology to assist with its ongoing ophthalmology trial program. On May 15, 2014, Ohr announced that it had entered into an agreement to acquire the ophthalmology assets of SKS Ocular LLC ("**SKS**"). *See* Press Release, Ohr Pharmaceutical, Inc., *Ohr Pharmaceutical Announces Agreement to Acquire Technology Assets of SKS Ocular* (May 15, 2014). As part of the acquisition, SKS's principals joined Ohr's management team: Glenn L. Stoller joined as CSO; Slakter joined as CMO; and Kaiser joined as Senior Vice President of Product Development. *Id.* At that time, Ohr failed to mention that Stoller had previously served as a principal investigator on Genaera's phase II trials of Squalamine as well

as that Genaera had determined that based on the data available from its trials that Squalamine was unlikely to produce vision improvement with the speed or frequency necessary to compete with Lucentis and that there was “no attractive or pragmatic option for the registration and commercialization of Evizon for the treatment of wet AMD[.]” *See id.*; Clinical Trial NCT00333476, Clinicaltrials.gov, <https://clinicaltrials.gov/ct2/show/NCT00333476> (last visited June 17, 2018).

## 2. Defendants Tout the IMPACT Trial’s Interim Results

54. On June 24, 2014, Ohr announced the Interim Results of the IMPACT Trial. The results showed that, for the visual acuity endpoint, the mean improvement in visual acuity for the Squalamine Arm was **10.4 letters**, whereas the mean improvement in visual acuity for the Lucentis Monotherapy Arm was **6.3 letters**, a **4.1 letter** difference between the two arms. *See* Press Release, Ohr Pharmaceutical, Inc., *Ohr Pharmaceutical Announces Positive Interim Top-line Clinical Results from Phase II Study of Squalamine Eye Drops in Patients with Wet AMD* (June 24, 2014). The Company touted these results as “**truly remarkable[.]**” explaining that “[v]isual acuity is the most clinically relevant endpoint for back-of-the-eye disorders. For wet-AMD patients, such enhanced gains of visual acuity over standard-of-care anti-VEGF treatments, and the restoration of vision lost to this devastating disease . . . **is a very important clinical outcome.**” *Id.*

55. Despite their praise for the results, Defendants failed to explain to the market that the only reason that the Interim Results showed a relative difference of 4.1-letters in visual acuity between the Squalamine Arm and the Lucentis Monotherapy Arm is that the visual acuity results for the Lucentis Monotherapy Arm underperformed the historical results observed in prior studies of Lucentis, including the studies that served as the basis for the FDA’s approval of Lucentis to treat Wet AMD. The chart below lists the results from prior studies of Lucentis

monotherapy in Wet AMD patients receiving the same dose of Lucentis as the patients in the IMPACT trial:<sup>12</sup>

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<sup>12</sup> See Philip J. Rosenfeld, M.D., et al., *Ranibizumab for Neovascular Age-Related Macular Degeneration*, 355 N. Engl. J. Med. 1419 (2006); David M. Le, et al., *Ranibizumab Versus Verteporfin for Neovascular Age-Related Macular Degeneration*, 355 N. Eng. J. Med. 1432 (2006); Geeta A. Lalwani, M.D., *All About PrONTO: Study Yielded Good Results in AMD With Treatment Guided by OCT*, Retina Today, May 2007; Lalwani GA, *A Variable-Dosing Regimen With Intravitreal Ranibizumab for Neovascular Age-Related Macular Degeneration: Year 2 of the PrONTO Study*, 148 Am. J. Ophthalmol. 43 (2009); Omesh P. Gupta MD et al., *A Treat and Extend Regimen Using Ranibizumab for Neovascular Age-Related Macular Degeneration: Clinical and Economic Impact*, 117 J. Ophtha. 2134 (2010); The CATT Research Group, *Ranibizumab and Bevacizumab for Neovascular Age-Related Macular Degeneration*, 364 N. Engl. J. Med. 1897 (2011); Oubrahim H, et al., *Inject and Extend Dosing Versus Dosing as Needed: a Comparative Retrospective Study of Ranibizumab in Exudative Age-related Macular Degeneration*, 31 Retina 26 (2011); Usha Chakravarthy, Ph.D., et al., *Ranibizumab versus Bevacizumab to Treat Neovascular Age-related Macular Degeneration*, 119 J. Ophtha. 1399 (2012); Jeffrey S. Heier, M.D., et al., *Intravitreal Aflibercept (VEGF Trap-Eye) in Wet Age-related Macular Degeneration*, 119 J. Ophtha. 2537 (2012); Daniel F. Martin, M.D., et al., *Ranibizumab and Bevacizumab for Treatment of Neovascular Age-Related Macular Degeneration: 2-Year Results*, 119 J. Ophtha. 1388 (2012); Jordi Mones et al., *FUSION Regimen: Ranibizumab in Treatment-Naïve Patients with Exudative Age-related Macular Degeneration and Relatively Good Baseline Visual Acuity*, 250 Graefes Arch. Clin. Exp. Ophthalmol. 1737 (2012); Busbee BG et al., *Twelve-Month Efficacy and Safety of 0.5mg or 2.0 mg. Ranibizumab in Patients With Subfoveal Neovascular Age-Related Macular Degeneration*, 120 J. Ophtha. 1046 (2013); Usha Chakravarthy, et al., *Alternative Treatments to Inhibit VEGF in Age-Related Choroidal Neovascularization: 2-Year Findings of the IVAN Randomised Controlled Trial*, 382 Lancet 1258 (2013); Damien McNamara, *Bevacizumab, Ranibizumab Comparable for Macular Degeneration*, Medscape (May 9, 2013); Laurent Kodjikian et al., *Ranibizumab versus Bevacizumab for Neovascular Age-related Macular Degeneration: Results from the GEFAL Noninferiority Randomized Trial*, 120 Ophtha. 2300 (2013); Isle Krebs et al., *A Randomised Double-Masked Trial Comparing the Visual Outcome After Treatment with Ranibizumab or Bevacizumab in Patients with Neovascular Age-Related Macular Degeneration*, 97 Brit. J. Ophtha. 266 (2013); David Faber et al, *Efficacy and Safety of 0.5 mg or 2.0 mg Ranibizumab in Patients with Wet Age-Related Macular Degeneration: HARBOR 2-Year Results*, 54 IOVS 6308 (2013); Caroline Helwick, *LUCAS Confirms Ranibizumab, Bevacizumab Comparable*, Medscape (Nov. 22, 2013); Ursula Schmidt-Erfurth, M.D. et al., *Intravitreal Aflibercept Injection for Neovascular Age-Related Macular Degeneration: Ninety-Six-Week Result of the VIEW Studies*, 121 Ophtha. 193 (2014); Irmela Mantel et al., *Reducing the Clinical Burden of Ranibizumab Treatment for Neovascular Age-related Macular Degeneration Using an Individually Planned Regimen*, 98 Brit. J. Ophtha. 1192 (2014); Ann-Sofie Marie Evelyn Schauwvlieghe et al., *Comparing the Effectiveness of Bevacizumab to Ranibizumab in patients with Exudative Age-Related Macular Degeneration. BRAMD*, 55 IOVS 870 (2014).

Study Name	Date of Publication	BCVA Improvement With Injections As Needed Per Set Protocol	BCVA Improvement With Monthly Injections
MARINA	2006	N/A	7.2 letters at 9 mos. 7.2 letters at 12 mos. 6.6 letters at 24 mos.
ANCHOR	2006	N/A	11.4 letters at 9 mos. 11.3 letters at 12 mos.
PrONTO	2007	9.3 letters at 12 mos. 11.1 letters at 24 mos.	N/A
A Treat and Extend Regimen Using Ranibizumab for Wet AMD: Clinical and Economic Impact	2010	9.7 letters at 24 mos.	N/A
Inject and Extend Dosing Versus Dosing as Needed	2011	2.3 letters at 12 mos. as needed 10.8 letters at 12 mos. inject & extend	N/A
CATT	2011	7.2 letters at 9 mos. 6.8 letters at 12 mos. 6.7 letters at 24 mos.	7.5 letters at 9 mos. 8.5 letters at 12 mos. 8.8 letters at 24 mos.
VIEW1	2012	N/A	8.1 letters at 12 mos.
VIEW2	2012	N/A	9.4 letters at 12 mos.
FUSION	2012	5.6 letters at 12 mos.	N/A
HARBOR	2013	8.2 letters at 12 mos. 7.9 letters at 24 mos.	10.1 letters in at 12 mos. 9.1 letters at 24 mos.
VIEW 96 Week Results	2013	7.9 letters at 22 mos	N/A
IVAN	2013	7.2 letters at 12 mos. <sup>13</sup> 4.9 letters at 24 mos.	
LUCAS	2013	8.2 letters at 12 mos.	N/A
GEFAL	2013	3.63 letters at 12 mos.	N/A
MANTA	2013	4.1 letters at 12 mos.	N/A

<sup>13</sup> The results for the Lucentis “as-needed” and “monthly” arms of the IVAN study were only reported in combination.

Study Name	Date of Publication	BCVA Improvement With Injections As Needed Per Set Protocol	BCVA Improvement With Monthly Injections
Reducing the clinical burden of ranibizumab treatment for neovascular age-related macular degeneration using an individually planned regimen	Apr. 2014	9.8 letters at 12 mos.	N/A
BRAMD	Apr. 2014	N/A	6.4 letters at 12 mos.
<b>Average for all trials:</b>	<b><u>7.94 letters</u></b>		

56. Thus, the data from other studies of Lucentis monotherapy showed that, on average, patients improved **7.94 letters** from baseline. Had the Lucentis Monotherapy Arm in the IMPACT Trial not underperformed prior Lucentis studies and achieved a vision gain of **7.94 letters**, the relative difference in vision improvement between the Squalamine Arm (**10.4 letters**) and the Lucentis Monotherapy Arm (**6.3 letters**) would shrink from **4.1 letters to 2.46 letters**, a decline of 40% – a number that is not a clinically meaningful difference.

57. Significantly, the term “clinically meaningful” is used to define whether a treatment provides a meaningful benefit on an aspect of how a patient feels, functions, or survives as a result of treatment. See Jessica J. Lee, MD, MMSc, *Defining Clinical Benefit in Clinical Trials: FDA Perspective*, FDA (2015). For a Wet AMD treatment to be clinically meaningful, the treatment must improve vision by **at least 4 letters**, according to Dr. David Boyer, a member of Ohr’s own Scientific Advisory Board. See Slingshots Insights Telephone Interview with Dr. David Boyer, Ophthalmologist (Dec. 29, 2015) (transcript available through Slingshot Insights, Inc.).

58. Defendants did not explain that the Lucentis Monotherapy Arm materially underperformed in the Interim Results; instead, they stated the ***opposite***, assuring the market that ***“the visual acuity gains for the placebo eye drop arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment.”*** See Press Release, Ohr



Pharmaceutical, Inc., *Ohr Pharmaceutical Announces Positive Interim Top-line Clinical Results from Phase II Study of Squalamine Eye Drops in Patients with Wet AMD* (June 24, 2014).

### 3. Defendants Hire a Stock Promoter To Hype the IMPACT Trial's Interim Results

59. To further tout the Interim Results, Ohr hired a second stock pumper named Vista. On June 26, 2014, two days after the Interim Results were announced—when Ohr's stock was trading at \$7.31 per share—Vista issued a “research report” raising its price target for Ohr from \$14 to \$31. *See* Ross Silver, *Ohr Pharmaceutical: Update of Coverage*, Vista Partners (June 26, 2014). In the report, Vista lauded the Interim Results and made grandiose claims regarding Squalamine's potential effect on the Wet AMD market. *Id.* Vista also noted that “[t]he Company believes that showing [visual acuity] improvements is far more meaningful to a wet AMD patient than reducing the number of injections . . .” *Id.*

60. That day, Vista also issued a press release promoting the Interim Results and reiterating that it had raised its price target. *See* Vista Partners LLC, *Vista Partners Updates Coverage on Ohr Pharmaceutical, Inc. (NASDAQ: OHRP); Raises Price Target to \$31* (June 26, 2014), <https://finance.yahoo.com/news/vista-partners-updates-coverage-ohr-130000341.html>. Notably, in violation of Section 17(b) of the Securities Act of 1933, 15 U.S.C. § 77q(b), Vista's press release never mentioned that it had been paid by Ohr to publish promotional materials. The research report, which was only referenced briefly in the press release, admitted in a small footnote on the last page though that:

This report has been prepared by Vista Partners LLC (“Vista”) with the assistance [sic] OHR Pharmaceutical, Inc. (“the Company”) based upon information provided by the Company. Vista has not independently verified such information, and in addition, Vista has been compensated by the Company for advisory services for a one year period.

*See* Ross Silver, *Ohr Pharmaceutical Report*, Vista Partners, LLC, 10 (June 26, 2014) <http://moxreports.com/wp-content/uploads/Vista-Partners-Ohr-Pharma-Report.pdf>.



61. Vista's press release was picked up and quoted by the media, and ***Ohr's stock price soared 60% in two days, from a low of \$6.86 to a high of \$10.97.*** See Andrew Meola, *Why Ohr Pharmaceuticals (OHRP) Stock is Soaring Today*, TheStreet (June 26, 2014), <https://www.thestreet.com/story/12758833/1/why-ohr-pharmaceuticals-ohrp-stock-is-soaring-today.html>; see also John Seward, *OHR Pharmaceutical Up 30%, Partly Recoups 2-Day Losing Streak* (June 26, 2014), <https://finance.yahoo.com/news/ohr-pharmaceutical-30-partly-recoups-184408448.html>. These media sources did not mention that ***Vista was paid by Ohr for its marketing services*** nor did they mention that ***Vista published unverified information received directly from Ohr.*** See *Id.*; see also Meola, *supra*.

62. With the stock price elevated due to the enthusiasm generated by Vista's publications and Defendants' false and misleading statements regarding the Interim Results, on February 6, 2015, Ohr priced a second public offering of 3,703,704 shares of common stock at \$6.75 per share for gross proceeds of approximately \$25 million. Ohr Pharmaceutical, Inc., Prospectus Supplement (Form 424B5) (Feb. 6, 2015). Cowen & Co., LLC served as the sole book runner and Brean Capital, LLC and LifeSci Capital, LLC served as the co-managers for the offering. *Id.*

#### 4. Defendants Tout the IMPACT Trial's Classic Lesions Results

63. Shortly thereafter, on March 27, 2015, Ohr touted the phase II IMPACT Trial's Classic Lesions Results. Press Release, Ohr Pharmaceutical, Inc., *Ohr Pharmaceutical Announces Final Topline Data From OHR-102 Phase II IMPACT Study in Wet-AMD* (Mar. 27, 2015). The announcement stated that the final results for 70 patients with classic-containing lesions included mean gains in visual acuity of ***10.5 letters*** in the Squalamine Arm and ***5.4 letters*** in the Lucentis Monotherapy Arm, a relative difference of ***5.1 letters*** between the two arms. *Id.*

64. The Company touted the visual acuity data for the Classic Lesions Results with Slakter stating that the 5.1 letter improvement in visual acuity in the Squalamine Arm “demonstrates *a positive and clinically meaningful treatment effect* of OHR-102 combination therapy in classic containing CNV” and with Taraporewala stating that “*there is a clear efficacy signal* in the classic AMD patient population[.]” Ohr Pharmaceutical Inc., Conference Call, Bloomberg Transcript, at 2 (Mar. 27, 2015).

65. When touting these results, Defendants failed to tell the market that the Lucentis Monotherapy Arm of the Classic Lesions Results *materially underperformed* in the IMPACT Trial. In prior Lucentis studies, Lucentis monotherapy patients experienced an average *7.94 letter improvement* in visual acuity. See ¶57. Thus, had patients in the Lucentis Monotherapy Arm of the Classic Lesions Results performed consistently with prior Lucentis studies and achieved vision gains of approximately 7.94 letters, the relative difference between the visual acuity gains for the Lucentis Monotherapy Arm (*5.4 letters*) and the Squalamine Arm (*10.5 letters*) for the Classic Lesions Results *would not be clinically meaningful*, as the difference would shrink from *5.1 letters* to *2.56 letters*, a decline of 50%. See ¶55, 57.

66. Rather than explaining these shortcomings in the data, Defendants spent the remainder of the Class Period promoting the Classic Lesions Results and discussing Ohr’s plans for a phase III trial based on the “positive” results.

67. During this time, Ohr appointed Slakter as CEO on August 7, 2015, and Taraporewala was transitioned to the role of Chief Technology Officer. Press Release, Ohr Pharmaceutical, Inc., *Ohr Pharmaceutical Reports Fiscal Third Quarter 2015 Financial and Business Results* (Aug. 6, 2015).

## 5. Defendants Tout the IMPACT Trial's Occult Lesions Results

68. Then, on May 11, 2015, Ohr touted the phase II IMPACT Trial's final Occult Lesions Results. Ohr explained that the new data demonstrated that even better visual acuity outcomes were seen in patients with small occult CNV lesions. *See* Press Release, Ohr Pharmaceutical, Inc., *Ohr Pharmaceutical Presents New Data from OHR-102 Phase II IMPACT Study in Wet-AMD At American Academy of Ophthalmology Annual Meeting* (Nov. 16, 2015). In the 94 patients with occult lesions of smaller than 10mm<sup>2</sup>, mean gains in visual acuity compared to baseline were **+11 letters** in the Squalamine Arm and **+5.7 letters** in the Lucentis Monotherapy Arm, a relative difference in visual acuity of **5.3 letters**. *Id.* Slakter hyped these results as “**robust**” and “**clinically meaningful**” and showing a “**dramatic effect in visual outcomes[.]**” *Id.*; Ohr Pharmaceutical, Inc., Conference Call, Seeking Alpha Transcripts (Dec. 10, 2015).

69. Defendants spent the remainder of the Class Period touting the Occult Lesions Results. Defendants never disclosed, however, that in previous Lucentis studies, patients receiving Lucentis experienced an average **7.94 letter improvement** in visual acuity. *See* ¶55. Had patients in the Lucentis Monotherapy Arm of the Occult Lesions Results performed consistently with prior Lucentis studies and achieved vision gains of 7.94 letters, the relative difference between the visual acuity gains for Lucentis Monotherapy Arm (**5.7 letters**) and the Squalamine Arm (**11 letters**) of the Occult Lesions Results **would not be clinically meaningful** because the difference between the two arms would have lowered from **5.3 letters** to **3.06 letters**, a decrease of 42% and again not a clinically meaningful result. *See* ¶55, 57.

## E. Defendants' Hype Ohr's Phase III MAKO Trial To Pump Up Ohr's Stock Price

70. On March 29, 2016, Ohr announced that it had initiated the MAKO Trial, its phase III trial for Squalamine in patients with Wet AMD. Press Release, Ohr Pharmaceutical,

Inc., *Ohr Pharmaceutical, Inc. Announces SPA Agreement With US FDA and Initiation of Phase III Wet AMD Clinical Program* (Mar. 29, 2016). The MAKO Trial was designed to enroll 650 patients with occult CNV lesions of 10mm<sup>2</sup> or smaller. *Id.* The trial was double-masked and patients would be randomly assigned to one of two arms: (1) in the Squalamine arm (*i.e.*, the treatment arm) where patients would receive an initial dose of Lucentis and would thereafter self-administer Squalamine eye drops twice daily while also receiving monthly injections of Lucentis; and (2) in the Lucentis arm (*i.e.*, the placebo control arm) where patients would receive an initial dose of Lucentis and would thereafter self-administer placebo eye drops twice daily while also receiving monthly injections of Lucentis. *See* Clinical Trial NCT02727881, ClinicalTrials.gov, <https://clinicaltrials.gov/ct2/show/study/NCT02727881> (last visited June 12, 2018). The primary endpoint was vision improvement. *See id.* Dr. David Brown, a retinal physician based in Houston, was appointed as the chair of the Steering Committee for the MAKO Trial, which was responsible for providing oversight and structure for the trial. *Id.*

71. After priming the market with the announcement of the MAKO Trial and the “positive” results from the IMPACT Trial, on December 7, 2016, Ohr conducted its third offering during the Class Period by entering into a purchase agreement whereby the Company agreed to issue and sell 3,885,000 shares of common stock, together with Series A warrants to purchase up to 1,942,500 shares of common stock and Series B warrants to purchase up to 3,885,000 shares of common stock, for net proceeds of \$6.9 million. Ohr Pharmaceutical, Inc., Current Report (Form 8-K, Item 1.01) (Dec. 8, 2016). H.C. Wainwright & Co., LLC served as the exclusive placement agent for the offering. *Id.*

72. By mid-2017, the Company was once again short on cash. The Company did not even have enough cash on hand to fund the MAKO Trial and again disclosed that there was “substantial doubt about [Ohr’s] ability to continue as a going concern.” Ohr Pharmaceutical,

Inc., Annual Report 9 (Form 10-K) (Dec. 15, 2017). As a result, on April 5, 2017, Ohr initiated its fourth offering of common stock in three years. Ohr entered into a purchase agreement whereby it agreed to sell 20,250,032 shares of common stock, together with warrants exercisable for up to 14,175,059 shares of common stock, for total proceeds of \$12.7 million. Ohr Pharmaceutical, Inc., Current Report (Form 8-K, Item 1.01) (Apr. 5, 2017). Rodman & Renshaw and Chardan Capital Markets, LLC served as co-lead placement agents for the offering. *Id.* This offering of \$12.7 million, along with the offerings on April 8, 2014 (\$18 million), February 9, 2015 (\$25 million), and December 7, 2016 (\$6.9 million), resulted in ***total proceeds to Ohr of \$62 million***, roughly 18 times the \$3.4 million in cash the Company had prior thereto. *See* ¶¶52, 62, 105.

73. During this time, Ohr began a promotional campaign to bring attention to the MAKO Trial, presenting at investor conferences and industry meetings, giving phone interviews, and speaking with analysts. *See* IR Calendar, Ohr Pharmaceutical, Inc., <https://ir.ohrpharmaceutical.com/ir-calendar> (last visited June 13, 2018); Sam Slutsky, *Company Update: Ohr Reports Third Quarter 2017 Financial Results; Data from MAKO Study Expected Early 2018*, LifeSci Capital, 1 (Aug. 9, 2017) (“August LifeSci Report”); Jason Slakter, *Ohr Expects to Release Top-Line Phase III Trials Next Year*, OIS (Aug. 21, 2017), <https://ois.net/ohr-pharmaceutical-to-release-top-line-phase-iii-trials/>; Yasmeen Rahimi, Ph.D., *OHRP YE17 Recap: Squaramine at the Finish Line While Others Dropped Like Flies*, Roth Capital Partners (Dec. 18, 2017).

74. During these presentations, Ohr continued to misrepresent the significance of the IMPACT Trial results and touted the likelihood of the MAKO Trial’s success. On July 12, 2017, Kaiser predicted a ***60% chance of success of the MAKO Trial***. *See* Sam Slutsky, *Company Update: Ohr Reports Third Quarter 2017 Financial Results; Data from MAKO Study Expected*

*Early 2018*, LifeSci Capital, 1 (August 9, 2017). The stock rose 11% the following day. Then, on December 18, 2017, Kaiser inexplicably upped his prediction to a **75 to 80% chance of success of the MAKO Trial**. See Yasmeen Rahimi, *Company Note: OHRP: Docs Are Bullish on the Success of MAKO Trial*; *Affirm Buy*, Roth Capital Partners, 1-2 (Dec. 19, 2017). The stock rose 5% the following day.

#### **F. The Phase III MAKO Trial Results**

75. Before the market opened on January 5, 2018, Ohr announced the that the Phase III MAKO Trial did not meet its primary efficacy endpoint of mean visual acuity. See Ohr Pharmaceutical, Inc., Press Release (Form 8-K, Ex. 99.1) (Jan. 5, 2018). In fact, ***patients receiving Squamamine eye drops performed worse than patients receiving placebo eye drops***. *Id.* “Subjects receiving ***Squamamine combination therapy (n=119) achieved a mean gain of 8.33 letters from baseline versus 10.58 letters from baseline with Lucentis® monotherapy* (n=118).” *Id.* On the news that Ohr’s study was an utter failure, Ohr’s common stock price declined \$1.64 per share from \$2.02 per share on January 4, 2018, to close at \$0.38 per share on January 5, 2018, ***a one-day drop of approximately 81.2%***.**

#### **FALSE AND MISLEADING CLASS PERIOD STATEMENTS<sup>14</sup>**

76. During the Class Period, Defendants made three categories of false and/or misleading statements:

- (a) Statements regarding the success of the previous phase II trials for Squamamine conducted by Genaera;
- (b) Statements regarding the mean visual acuity improvement observed in the IMPACT Trial’s Interim Results; and

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<sup>14</sup> The bolded and italicized (or otherwise highlighted) statements in this section are those statements alleged to be false and/or misleading.

- (c) Statements regarding the mean visual acuity improvement observed in the IMPACT Trial's Classic Lesions Results and the IMPACT Trial's Occult Lesions Results.

**A. False And Misleading Statements Regarding Genaera's Prior Clinical Trials Of Squalamine**

77. The Class Period begins on April 8, 2014 when Ohr filed its prospectus supplement with the SEC on Form 424B5 for an offering of 1,800,000 shares, which ultimately raised proceeds of approximately \$18 million. The prospectus supplement stated in relevant part:

*In Phase II clinical trials using the intravenous formulation of Squalamine, stabilization or improvement in visual activity was observed in the vast majority of patients, with both early and advanced lesions responding and few drug-related ocular or systemic effects observed. In a number of patients whose wet-AMD had progressed to an advanced stage, the administration of Squalamine produced beneficial effects and significant improvement in best corrected visual acuity.* As opposed to the approved current standard of care therapy, Squalamine does not require direct injection into the eye.

\* \* \*

*Using an intravenous formulation in over 250 patients in Phase I and Phase II trials for the treatment of Wet-AMD, the trials demonstrated that the molecule had biological effect and maintained and improved visual acuity outcomes,* with both early and advanced lesions responding.

78. On April 29, 2014 and May 9, 2014, Ohr issued press releases with updates on its clinical trial program. The press releases stated in relevant part:

*The drug, using an intravenous administration in over 250 patients in Phase I and Phase II trials for the treatment of wet-AMD, showed favorable biological effect and maintained and improved visual acuity outcomes.*

79. On May 13, 2014, Ohr filed its quarterly financial report for the second quarter of 2014 with the SEC on Form 10-Q ("2Q 2014 10-Q"). The 2Q 2014 10-Q was signed by Taraporewala and Backenroth and contained the same misleading statements as the 2014

Prospectus Supplement set forth in ¶¶77 above.

80. On June 2, 2014, Ohr issued a press release announcing the closing of its SKS acquisition. The press release contained the same misleading statement as the press releases issued on April 29, 2014 and May 9, 2014.

81. The statements in ¶¶77-80 above were false and/or misleading when made because the speaker knowingly or recklessly omitted the following material facts that deceived investors as to the results of Genaera's clinical trials of Squalamine in Wet AMD and Squalamine's prospects as a treatment for Wet AMD:

- (a) Genaera's prior clinical trials of Squalamine did not demonstrate that Squalamine had a favorable biological effect or improved visual acuity outcomes;
- (b) Genaera terminated its development of Squalamine for the treatment of Wet AMD because Genaera's trial demonstrated that Squalamine was unlikely to produce vision improvement with the speed or frequency necessary to compete with Lucentis and that there was "no attractive or pragmatic option for the registration and commercialization of Squalamine for the treatment of wet AMD," as set forth in ¶40; and
- (c) Genaera's phase II trials for Squalamine resulted in vision gains far inferior to those produced by Lucentis. In Genaera's Study 209, only 5% of subjects treated with 40 mg of Squalamine gained vision and only 4% of subjects treated with 20 mg of Squalamine gained vision, whereas, in the trials used to support FDA approval of Lucentis, 40% of patients treated with Lucentis gained vision, as set forth in ¶39.



**B. False And Misleading Statements Regarding the IMPACT Trial's Interim Results**

82. On June 24, 2014, Ohr announced “*positive*” interim results for the first 62 patients enrolled in the IMPACT Trial. In the press release announcing the results, the Company and Slakter stated:

Ohr Pharmaceutical, Inc. (Nasdaq:OHRP), an ophthalmology research and development company, today *announced positive top-line interim results for its double-masked, placebo-controlled Phase II clinical trial of Squalamine eye drops in patients with wet age-related macular degeneration (wet AMD). The data demonstrated a positive benefit in visual function across multiple clinically relevant endpoints, including a mean change in visual acuity at the end of study visit for the interim analysis group of +10.4 letters with Squalamine eye drops plus Lucentis® PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit (p=0.18).*

The Squalamine-treated group demonstrated improved best-corrected visual acuity (BCVA) gains relative to the placebo group at all timepoints evaluated from four to 38 weeks. In the interim analysis group, 48.3 percent of Squalamine-treated patients showed BCVA gains of  $\geq 15$  letters ( $\geq 3$  lines) on a standard ETDRS eye-chart, compared with 21.2 percent in the placebo arm at the end of the study ( $p=0.025$ ). In addition, patients receiving Squalamine drops were more than twice as likely to gain  $\geq 4$  and  $\geq 5$  lines of vision compared with patients in the placebo eye drop arm ( $\geq 4$  lines  $p=0.022$ ,  $\geq 5$  lines  $p=0.059$ ). *Importantly, the visual acuity gains for the placebo eye drop arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment.* . . .

“*The beneficial effects of Squalamine on visual acuity that we’ve seen thus far, through its inhibition of multiple angiogenic growth factors and pathways, and in particular, the improvement in gains of three or more lines in vision compared with the placebo group, are truly remarkable,*” said Dr. Jason Slakter[.]

83. In the power point presentation accompanying the announcement, the Company stated:

Conclusions:

- *Squalamine eye drops combined with Lucentis PRN demonstrated marked improvements over the Lucentis PRN + placebo drops in:*
  - *Mean gains in Visual Acuity (p=0.18)*
  - *% of patients gaining  $\geq 15$  letters (p=0.025)*
  - *% of patients with  $\geq 4$  and  $\geq 5$  line vision gain (p=0.022 and p=0.059)*

Summary:

- ***The interim results of the Squalamine eye drop program demonstrate dramatic vision gains across the full spectrum of exudative AMD compared to Lucentis + placebo drop regimen***

84. On August 13, 2014, Ohr issued a press release announcing that it had presented additional interim IMPACT trial results at the annual meeting of the American Society of Retinal Specialists. In the press release, the Company stated:

***The data demonstrated a visual acuity and anatomical benefit for the group of patients receiving the combination of OHR-102 and Lucentis® PRN (“OHR-102 arm”) versus placebo eye drops plus Lucentis PRN (“Lucentis monotherapy arm”). . . .***

***The OHR-102 treated group demonstrated improved best-corrected visual acuity (BCVA) gains relative to the Lucentis monotherapy group*** at all timepoints evaluated from four to 38 weeks. In the interim analysis group, 48.3 percent of OHR-102 treated patients showed BCVA gains of  $\geq 15$  letters ( $\geq 3$  lines) on a standard ETDRS eye-chart, compared with 21.2 percent in the monotherapy arm at the end of the study ( $p=0.025$ ). In addition, patients receiving OHR-102 drops were more than twice as likely to gain  $\geq 4$  and  $\geq 5$  lines of vision compared with patients in the Lucentis monotherapy arm ( $\geq 4$  lines  $p=0.022$ ,  $\geq 5$  lines  $p=0.059$ ). ***Mean gain in visual acuity was +10.4 letters in the OHR-102 arm vs. +6.3 letters in the Lucentis monotherapy arm ( $p=0.18$ ).***

***Importantly, the visual acuity gains for the Lucentis monotherapy arm were consistent with those observed in previous clinical studies using Lucentis monotherapy treatment.***

85. On August 18, 2014, Ohr filed its quarterly financial report for the third quarter of 2014 with the SEC on Form 10-Q (“3Q 2014 10-Q”). The 3Q 2014 10-Q was signed by Taraporewala and Backenroth and stated:

***The data demonstrated a positive benefit in clinically relevant visual function in the OHR-102 arm across multiple key secondary endpoints. . . .*** In the interim analysis group, 48.3 percent of OHR-102 treated patients showed best corrected visual acuity (“BCVA”) gains of  $\geq 15$  letters ( $\geq 3$  lines) on a standard early treatment diabetic retinopathy study eye-chart, compared with 21.2 percent in the Lucentis monotherapy arm at the end of the study ( $p=0.025$ ). In addition, patients receiving OHR-102 drops were more than twice as likely to gain  $\geq 4$  and  $\geq 5$  lines of vision compared with patients in the Lucentis monotherapy arm ( $\geq 4$  lines  $p=0.022$ ,  $\geq 5$  lines  $p=0.059$ ). ***Mean change in visual acuity at the end of***

*study visit was +10.4 letters with OHR-102 eye drops plus Lucentis PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit (p=0.18).*

86. On December 22, 2014, Ohr issued a press release announcing its financial results for the year ended September 30, 2014. In the press release, the Company and Taraporewala stated:

*“Treatment with OHR-102 demonstrated an improvement in visual acuity, the most clinically relevant endpoint for back-of-the-eye disorders. . . . The positive IMPACT data and successful outcome of our recent FDA meeting give us a clear path for future registration studies for OHR-102[,]”* stated Dr. Irach Taraporewala[.]

*The data demonstrated a positive benefit in clinically relevant visual function in the OHR-102 arm across multiple key secondary endpoints. . . .* In the interim analysis group, 48.3 percent of OHR-102 treated patients showed best corrected visual acuity (BCVA) gains of  $\geq 15$  letters ( $\geq 3$  lines) on a standard early treatment diabetic retinopathy study eye-chart, compared with 21.2 percent in the Lucentis monotherapy arm at the end of the study (p=0.025). Patients receiving OHR-102 drops were more than twice as likely to gain  $\geq 4$  and  $\geq 5$  lines of vision compared with patients in the Lucentis monotherapy arm ( $\geq 4$  lines p=0.022,  $\geq 5$  lines p=0.059). *Mean change in visual acuity at the end of study visit was +10.4 letters with OHR-102 eye drops plus Lucentis PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit (p=0.18).*

87. On December 22, 2014, Ohr filed its annual report for the fiscal year ended September 30, 2014 with the SEC on Form 10-K (“2014 10-K”). The 2014 10-K was signed by Taraporewala and Backenroth and stated in relevant part:

*The data demonstrated a positive benefit in clinically relevant visual function in the OHR-102 arm across multiple key secondary endpoints.* In the interim analysis group, 48.3 percent of OHR-102 treated patients showed best corrected visual acuity (“BCVA”) gains of  $\geq 15$  letters ( $\geq 3$  lines) on a standard early treatment diabetic retinopathy study eye-chart, compared with 21.2 percent in the Lucentis monotherapy arm at the end of the study (p=0.025). . . . In addition, patients receiving OHR-102 drops were more than twice as likely to gain  $\geq 4$  and  $\geq 5$  lines of vision compared with patients in the Lucentis monotherapy arm ( $\geq 4$  lines p=0.022,  $\geq 5$  lines p=0.059). *Mean change in visual acuity at the end of study was +10.4 letters with OHR-102 eye drops plus Lucentis PRN versus +6.3 letters in the placebo eye drops plus Lucentis PRN arm, a 65 percent additional relative benefit (p=0.18).*

88. That same day the Company held a conference call to discuss the financial results for the year ended September 30, 2014. During the call, Slakter and the Company stated in relevant part:

***The results of this interim analysis showed that Squalamine Eye Drops, in conjunction with Lucentis, provided substantial gains in visual acuity in this patient population, exceeding the visual acuity gains seen in the group receiving Lucentis alone. More specifically, this interim analysis data showed a mean gain in visual acuity of 10.4 letters with Squalamine Eye Drops plus Lucentis PRN, versus 6.3 letters in the placebo eye drop plus PRN Lucentis arm at the end of the nine-month study. This represents a 65% additional relative benefit in vision gain.***

89. On February 5 and 6, 2015, Ohr filed a prospectus supplement with the SEC on Form 424B5 for its offering of 3,703,704 shares of common stock, for total proceeds of approximately \$25 million. The prospectus contained the same false and misleading statements as the 2014 10-K, set forth in ¶87 above.

90. On February 9, 2015, Ohr issued a press release announcing the financial results for its first quarter of 2015. The press release stated in relevant part:

***Data showing topical administration of OHR-102 used in combination with Lucentis® demonstrated marked improvements over Lucentis monotherapy in multiple visual acuity parameters in the IMPACT study.***

91. On February 9, 2015, Ohr filed its financial report for the first quarter of 2015 with the SEC on Form 10-Q (“1Q 2015 10-Q”). The 1Q 2015 10-Q was signed by Taraporewala and Backenroth and contained the same false and misleading statements as the 2014 10-K set forth in ¶87 above.

92. The statements in ¶¶82-91 above were false and/or misleading when made because the speaker knowingly or recklessly omitted the following material facts that deceived investors as to the IMPACT Trial’s Interim Results and Squalamine’s likelihood of success in treating Wet AMD:

- (a) The 6.3-letter visual acuity gain observed in the Lucentis Monotherapy Arm of the IMPACT Trial’s Interim Results underperformed the mean 7.94-letter gain observed in prior studies of Lucentis monotherapy treatment;
- (b) Had the Lucentis Monotherapy Arm in the IMPACT Trial’s Interim Results performed as well as the Lucentis monotherapy arms in prior studies of Lucentis, the relative improvement for the Squalamine Arm compared to the Lucentis Monotherapy Arm would only have been a negligible 2.46 letter improvement—a difference that is not clinically meaningful.
- (c) Had the Lucentis Monotherapy Arm in the IMPACT Trial’s Interim Results performed as well as the Lucentis monotherapy arms in prior studies of Lucentis, the additional relative benefit for the Squalamine Arm compared to the Lucentis Monotherapy Arm would only have been 31% (as opposed to the 65% asserted in ¶88); and
- (d) As a result of (a), (b), and (c), the visual acuity results observed in the Squalamine Arm of the IMPACT Trial’s Interim Results were neither “truly remarkable” (¶82) nor did they show “dramatic vision gains” (¶83), “substantial gains” (¶88), a “positive benefit in clinically relevant visual function” (¶¶ 82, 85-87) or “marked improvements” (¶90).

**C. False And Misleading Statements Regarding The IMPACT Trial’s Classic Lesions Results and Occult Lesions Results**

93. On March 27, 2015, Ohr issued a press release announcing the “positive” final data from the IMPACT trial. In the press release, the Company stated as follows concerning the Classic Lesions Results:

***Positive Visual Acuity Benefit in Classic Containing CNV Using OHR-102 Combination Therapy . . .***

***In patients with classic CNV (ITT-LOCF), mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.1 letters.***

94. On that same day, Ohr held a conference call to discuss the IMPACT trial's final results. During the conference call, Slakter and the Company stated in relevant part concerning the Classic Lesions Results:

In the intent-to-treat analysis, which includes last observation carried forward, in the population with classic containing CNV, we observed that 42% of the patients receiving OHR-102 achieved a three-line or greater gain in vision at nine months as compared to 28% in the Lucentis monotherapy group. ***With respect to mean gains in visual acuity, we observed a 10.5 letter gain in the OHR-102 combination arm versus 5.4 letters gain in Lucentis monotherapy group***

This is a 5.1 letter benefit for the OHR-102 treated patients. ***These data demonstrate a positive and clinically meaningful treatment effect of OHR-102 combination therapy in classic containing CNV using a PRN treatment regimen and are consistent with historical combination therapy studies in this same patient population.***

\*\*\*

What's really important to keep in mind is that we now have ***a fully completed Phase II study with 142 patients that demonstrates a positive and clinically meaningful treatment effect of OHR-102 combination therapy in classic containing CNV.*** We had the opportunity to share our analysis with our Scientific Advisory Board, and they are in agreement with our conclusion and fully support the development path forward for OHR-102.

95. On May 7, 2015, Ohr issued a press release announcing additional data from the IMPACT trial. In the press release, the Company and Slakter stated as follows concerning the Classic Lesion Results:

***In the mITT population with lesions containing classic choroidal neovascularization (classic containing lesions) (OHR-102 n=37, Lucentis® monotherapy n=28), mean gains in visual acuity at month nine were +11 letters for the OHR-102 combination arm and +5 letters with Lucentis monotherapy, a clinically meaningful benefit of 6 letters. . . .***

***“The results from the IMPACT study demonstrate that topically administered OHR-102 combination therapy can lead to improved visual function*** in patients with wet AMD and, importantly, that the efficacy results may be determined by lesion size and composition,” stated Dr. Jason Slakter, Chief Medical Officer at Ohr. ***“There was a clear and clinically meaningful benefit in patients whose lesions contained some classic CNV.”***

96. On May 11, 2015, Ohr filed its financial report for the second quarter of 2015 with the SEC on Form 10-Q (“2Q 2015 10-Q”). The 2Q 2015 10-Q was signed by Taraporewala and Backenroth and stated in relevant part concerning the Classic Lesion Results:

Data from the IMPACT study demonstrated that, in that the intent-to-treat (ITT-LOCF) population with classic containing choroidal neovascularization (CNV) (OHR-102 n=38, Lucentis® monotherapy n=32), 42% of the patients receiving OHR-102 achieved a  $\geq 3$  line gain at nine months, as compared to 28% in the Lucentis monotherapy group. In patients with classic CNV (ITT-LOCF), ***mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.1 letters.***

97. That same day the Company held a conference call to discuss the quarterly results. During the conference call, Ohr, Taraporewala, and Slakter discussed the IMPACT trial results, stating as follows concerning the Classic Lesion Results and Occult Lesions Results:

[Taraporewala]: ***patients in the study with classic containing choroidal neovascularization or CNV treated with the OHR- 102 plus Lucentis combination achieved a clinically meaningful improvement in visual acuity, compared with those who received Lucentis alone. The positive effects of visual acuity in classic CNV were seen early in the course of treatment, and continued to increase to the end of the study.*** This benefit is consistent with both the mechanism of OHR-102, and historical combination therapy studies.

[Slakter]: We recognize now that the IMPACT study demonstrated that classic containing lesions achieve a marked visual acuity benefit with combination therapy with OHR-102 and Lucentis on a PRN basis. These results mirror results from other combination therapy trials in patients with classic containing lesions. . . .

[A] post hoc analysis of 94 of the 128 patients who completed the nine months of the trial who had an area of occult CNV at baseline of a less than 10 square millimeters or about four disk areas. ***As you will see a significant difference in outcome between the two treatment groups is noted. This includes patients with both classic containing as well as occult-only lesions. With OHR-***



*102 combination therapy, there is a gainable 11 letters at month nine versus a 5.7 letter gain in the Lucentis monotherapy group, a difference of 5.3 letters. . . .*

*[Y]ou're seeing combination therapy showing biologically active and clinically meaningful results, compared to anti-VEGF monotherapy.*

98. On August 6, 2015, Ohr issued a press release announcing its financial results for the third quarter of 2015. In the press release the Company discussed the IMPACT trial results, stating in relevant part concerning the Classic Lesion Results and Occult Lesions Results:

*Patients with classic containing CNV demonstrated a mean gain in visual acuity at month nine of +11 letters for the OHR-102 combination arm and +5 letters with Lucentis® monotherapy, a clinically meaningful benefit of 6 letters.*

*Patients with an occult CNV area less than 10mm<sup>2</sup>, regardless of classic CNV being present, treated with the combination of OHR-102 and Lucentis PRN, demonstrated a positive visual acuity benefit compared to the Lucentis monotherapy arm which was similar to that seen in the classic containing CNV population.*

99. On August 11, 2015, Ohr filed its financial report for the third quarter of 2015 with the SEC on Form 10-Q ("3Q 2015 10-Q"). The 3Q 2015 10-Q was signed by Taraporewala and Backenroth and contained the same misleading statements as the 2Q 2015 10-Q set forth in ¶96 above.

100. On December 10, 2015, Ohr issued a press release announcing the financial results for the fiscal year ended September 30, 2015. In the press release, the Company and Slakter stated in relevant part concerning the Classic Lesion Results and Occult Lesions Results:

*"We successfully completed the Phase 2 IMPACT study in patients with wet AMD, demonstrating a positive and clinically meaningful treatment effect with OHR-102 combination therapy.* The various analyses we conducted of the IMPACT data, which were featured at major ophthalmology meetings in the U.S. and internationally through the year, gave us insight into the mechanism of action of OHR-102 and identified the patients most likely to benefit from OHR-102 combination therapy."

"The strong body of clinical evidence we have accumulated supports our conviction that OHR-102 combination therapy has the potential to establish a new standard of care in wet AMD," continued Dr. Slakter. . . .



***In patients with classic CNV (ITT-LOCF), mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis® (anti-VEGF) monotherapy, a clinically meaningful benefit of +5.1 letters. . . .***

***Mean gains in visual acuity compared to baseline were +11.0 letters for the OHR-102 plus Lucentis combination arm and +5.7 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.3 letters in this occult <10mm<sup>2</sup> population.***

101. On February 9, 2016, Ohr filed its financial report for the first quarter of 2016 with the SEC on Form 10-Q (“1Q 2016 10-Q”). The 1Q 2016 10-Q was signed by Slakter and Backenroth and discussed the IMPACT trial results, stating in relevant part concerning the Classic Lesion Results and Occult Lesions Results:

***In patients with classic CNV (ITT-LOCF), mean gains in visual acuity were +10.5 letters for the OHR-102 combination arm and +5.4 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.1 letters.*** The positive effect on visual acuity in classic CNV was seen early in the course of treatment and continued to increase through the end of the study. . . .

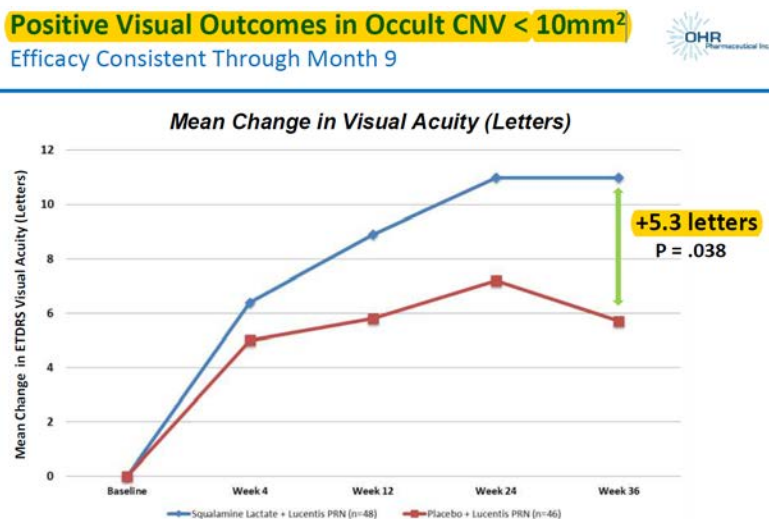
***In those patients with occult CNV less than 10mm<sup>2</sup> in area (n=94 of 128 completing study), 40% of those treated with OHR-102 combination therapy achieved a gain of 3 or more lines of vision, compared with 26% of patients in the Lucentis monotherapy arm, a 54% additional benefit. In addition, mean gains in visual acuity compared to baseline were +11.0 letters for the OHR-102 combination arm and +5.7 letters with Lucentis monotherapy, a clinically meaningful benefit of +5.3 letters.***

Importantly, this group of patients represents a larger proportion of the subjects enrolled in the IMPACT study than the classic containing group.

102. On May 10, 2016, Ohr filed its financial report for the second quarter of 2016 with the SEC on Form 10-Q (“2Q 2016 10-Q”). The 2Q 2016 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q set forth in ¶101.

103. On August 9, 2016, Ohr filed its financial report for the third quarter of 2016 with the SEC on Form 10-Q (“3Q 2016 10-Q”). The 3Q 2016 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q set forth in ¶101.

104. On October 13, 2016, Slakter and the Company presented at the Ophthalmology Innovation Summit hosted by American Academy of Ophthalmology. Slakter's presentation was accompanied by power point slides. The slides stated in relevant part concerning the Occult Lesions Results:



### Squalamine Lactate Ophthalmic Solution Summary

- Squalamine has the potential to be a convenient and cost-effective therapy in retinal disease
- Indication in Exudative AMD**
  - Unmet need for improved vision beyond anti-VEGF monotherapy
  - Strong phase 2 data supporting role of squalamine combination therapy in providing clinically meaningful vision gains
- Use with Multiple Anti-VEGF Agents
  - Combination effect with all current and future anti-VEGF agents
  - Topical delivery adaptable for use with any anti-VEGF treatment regimen/frequency
- Multiple back-of-the-eye indications
  - Initial data in investigator led clinical trial evaluating retinal vein occlusion indicate improved vision outcomes
  - Suggests potential role in retinal vascular disease (RVO and DME)

105. On December 8 and 9, 2016, Ohr filed a prospectus supplement with the SEC on Form 424B5 for its offering of 3,885,000 shares of common stock, for total proceeds of approximately \$6.9 million. The prospectus supplement contained the same misleading statements as the 1Q 2016 10-Q set forth in ¶101 above.

106. On December 22, 2016, Ohr filed its annual report for the fiscal year ended September 30, 2016 with the SEC on Form 10-K (“2016 10-K”). The 2016 10-K was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q set forth in ¶101 above.

107. On February 14, 2017, Ohr filed its financial report for the first quarter of 2017 with the SEC on Form 10-Q (“1Q 2017 10-Q”). The 1Q 2017 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q set forth in ¶101.

108. On April 4 and 6, 2017, Ohr filed a prospectus supplement with the SEC on Form 424B5 for its offering of 20,250,032 shares of common stock, for total proceeds of approximately \$12.7 million. The prospectus supplement contained the same misleading statements as the 1Q 2016 10-Q set forth in ¶101.

109. On May 11, 2017, Ohr filed its financial report for the second quarter of 2017 with the SEC on Form 10-Q (“2Q 2017 10-Q”). The 2Q 2017 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q set forth in ¶101.

110. On August 8, 2017, Ohr filed its financial report for the third quarter of 2017 with the SEC on Form 10-Q (“3Q 2017 10-Q”). The 3Q 2017 10-Q was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q set forth in ¶101.

111. On December 15, 2017, Ohr filed its annual report for the fiscal year ended September 30, 2017 with the SEC on Form 10-K (“2017 10-K”). The 2017 10-K was signed by Slakter and Backenroth and contained the same misleading statements as the 1Q 2016 10-Q set forth in ¶101 above.

112. The statements in ¶¶93-111 above were false and/or misleading when made because the speaker knowingly or recklessly omitted the following material facts that deceived investors as to the IMPACT Trial’s final Classic Lesions Results and Occult Lesions Results and

Squalamine's likelihood of success in treating Wet AMD:

- (a) The visual acuity gains observed in the Lucentis Monotherapy Arms of the Classic Lesions Results (5.4 letters) and the Occult Lesions Results (5.7 letters) underperformed the mean 7.94-letter gain observed in prior studies of Lucentis monotherapy treatment;
- (b) Had the Lucentis Monotherapy Arms of the Classic Lesions Results and the Occult Lesions Results performed as well as the Lucentis treatment arms in prior studies of Lucentis, the relative improvement for the Squalamine Arms compared to the Lucentis Monotherapy Arms would have only been a negligible 2.56 letter improvement for the Classic Lesions Results and a 3.06 letter improvement for the Occult Lesions Results—neither of which is a clinically meaningful difference.

#### **POST CLASS PERIOD EVENTS**

113. Before the market opened on January 5, 2018, Ohr announced that the Phase III MAKO study did not meet its primary efficacy endpoint of mean visual acuity gain. *See* Ohr Pharmaceutical, Inc., Press Release (Form 8-K, Ex. 99.1) (Jan. 5, 2018). In fact, patients receiving Squalamine eye drops in the Squalamine arm performed worse than patients receiving placebo eye drops in the Lucentis arm. *Id.* “Subjects receiving Squalamine combination therapy (n=119) achieved a mean gain of 8.33 letters from baseline versus 10.58 letters from baseline with Lucentis® monotherapy (n=118).” *Id.*

114. On this news, the Company's common stock price declined \$1.64 per share from a close on January 4, 2018 at \$2.02 per share, to a close of \$0.38 per share on January 5, 2018, a drop of approximately 81.2%.

## **ADDITIONAL SCIENTER ALLEGATIONS**

### **A. *Respondeat Superior* And Agency Principles Apply**

115. Ohr is liable for the acts of Ohr's and any subsidiary's officers, directors, employees, and agents under the doctrine of *respondeat superior* and common law principles of agency as all of the wrongful acts complained of herein were carried out within the scope of their employment or agency with the authority or apparent authority to do so. The scienter of Ohr's officers, directors, employees, and agents is similarly imputed to Ohr under *respondeat superior* and agency principles.

### **B. Defendants Had Possession Of Or Access To Information That Contradicted Their Public Statements Regarding Genaera's Prior Squalamine Trials**

116. Ohr and the Individual Defendants, as officers of the Company, had possession of or access to information showing that the Squalamine trials conducted by Genaera were not successful because Glen Stoller, Ohr's CSO since May 2014, and Thomas Ciulla, a member of Ohr's Scientific Advisory Board from at least November 2013 to the end of 2015, both worked as investigators on Genaera's phase II trials. *See* Clinical Trial NCT00333476, Clinicaltrials.gov, <https://clinicaltrials.gov/ct2/show/NCT00333476> (last visited June 17, 2018). Thomas Ciulla was also selected to serve as an investigator for Genaera's phase III trials of Squalamine that the company never initiated. *See* Clinical Trial NCT00139282, Clinicaltrials.gov, <https://clinicaltrials.gov/ct2/show/NCT00139282> (last visited June 17, 2018).

117. Furthermore, when Ohr acquired all of the rights to Squalamine from Genaera, it acquired all of the previous clinical trial data and Genaera's analyses and determinations regarding the data. *See* ¶43; Ohr Pharmaceutical, Inc., Asset Purchase Agreement (Ex. 10.1) 3, 6 (Aug. 26, 2009). Thus, Ohr and the Defendants were in possession of and had access to the poor results from the Genaera trials showing that Squalamine did not improve patients' vision and were undoubtedly aware of Genaera's decision to abandon Squalamine.

**C. Defendants Had Possession Of Or Access To Information That Contradicted Their Public Statements Regarding The Significance Of The IMPACT Trial's Results**

118. As officers of the Company, all of the Individual Defendants had access to the Interim Results and the IMPACT Trial's final results, including the Classic Lesions Results and the Occult Lesions Results.

119. Ohr and the Individual Defendants were also admittedly aware of the results from prior studies of Lucentis as a monotherapy. For example, on the December 22, 2016 earnings conference call, Slakter admitted:

*When we first evaluated our phase 2 data, one of the first things we looked at was how closely our Lucentis monotherapy control arm performed compared to prior studies.*

Ohr Pharmaceutical Inc., Conference Call, Bloomberg Transcript (Dec. 22, 2016). Similarly, an analyst noted that Dr. Kaiser stated in a call that he was bullish on the MAKO Trial and predicted there was a 75-80% chance that it would succeed because, *inter alia*, “the strong agreement in the placebo arm in the IMPACT trial versus the placebo arm across other Lucentis trials[.]” See Yasmeen Rahimi, *Company Note: OHRP: Docs Are Bullish on the Success of MAKO Trial; Affirm Buy*, Roth Capital Partners, 1 (Dec. 19, 2017). These statements indicate that Kaiser and Slakter, along with the other members of Ohr's management team, did in fact look at the results from the prior Lucentis studies before making statements regarding the Interim Results, the Classic Lesions Results, and the Occult Lesions Results

120. Furthermore, as indicated in the chart below, many of Ohr's officers and advisors were involved in the prior Lucentis studies and thus would have known the outcomes of those studies and communicated the information to others as the Company:

Study	Year	Insiders
ANCHOR	2006	Kaiser, Brown, Heier <sup>15</sup>
MARINA	2006	Kaiser, Brown, Boyer Heier
VIEW1 and VIEW2	2012	Kaiser, Brown, Heier
HARBOR	2013	Brown, Heier
VIEW 96-Week Follow Up	2013	Kaiser, Brown, Slakter, Heier

121. Brown served as the head of the steering committee for the MAKO Trial; Heier and Boyer have served as members of Ohr's Scientific Advisory Board since at least November 2013; Kaiser is Ohr's Head of Product Development; and Slakter is Ohr's CEO.

122. Slakter confirmed that the Company consulted with the Scientific Advisory Board regarding the IMPACT Trial results and the Board provided insight regarding the results: "We had the opportunity to share our analysis with our Scientific Advisory Board, and they are in agreement with our conclusion and fully support the development path forward for OHR-102[.]" Ohr Pharmaceutical, Inc., Conference Call, Bloomberg Transcript (Mar. 27, 2015). Thus, given their vast experience with Lucentis, Heier and Boyer undoubtedly explained their knowledge regarding the prior Lucentis monotherapy studies to Defendants during those discussions.

123. As well, on a December 22, 2014 conference call, Slakter stated that "we are using the same 23 investigators' insight" to design the Phase III trial. Ohr Pharmaceutical, Inc., Conference Call, Bloomberg Transcript (Dec. 22, 2014). Slakter was referring to the 23 investigators that who conducted the IMPACT Trial. Boyer and Heier both served as investigators for the IMPACT Trial and thus, in addition to providing Ohr with information regarding Lucentis via their roles as members of Ohr's Scientific Advisory Board, they also

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<sup>15</sup> "Heier" refers to Jeffrey S. Heier, M.D., an ophthalmologist based in Boston who has served as a member of Ohr's Scientific Advisory Board since at least November 2013. Scientific Advisory Board, Ohr Pharmaceutical, Inc., [www. https://www.ohrpharmaceutical.com/about-ohr/scientific-advisory-board](https://www.ohrpharmaceutical.com/about-ohr/scientific-advisory-board) (last visited June 17, 2018). "Boyer" refers to David S. Boyer, M.D., an ophthalmologist based in Los Angeles who has served as a member of Ohr's Scientific Advisory Board since at least November 2013. *See id*

would have provided Ohr with their knowledge regarding Lucentis at this time. *See* Clinical Trial NCT01678963, Clinicaltrials.gov, <https://clinicaltrials.gov/ct2/show/NCT01678963> (last visited June 17, 2018).

**D. The Company's Financial Motives**

124. Unlike most companies, Defendants were highly motivated to keep the Company's stock price high during the Class Period in order to raise desperately needed capital to stave off bankruptcy.

125. Because the Company has never had a drug approved for marketing by the FDA, in 2013 and again in 2017, the Company disclosed that Ohr's auditor had "substantial doubt about our ability to continue as a going concern." *See* ¶¶47, 72. Thus, the Company needed to raise capital in order to continue operations and complete its trials of Squalamine.

126. Beginning in 2009 and continuing through the Class Period, Ohr repeatedly paid third parties to promote the Company's stock in order to draw attention to its clinical trial program. *See* ¶¶43, 59-61. These videos, presentations, and reports had the effect of leading the market to believe that Squalamine had garnered industry acceptance and that qualified analysts had found the results from the IMPACT Trial to be meaningful. In particular, two days after the Interim Results were announced, Defendants enlisted Vista to issue a promotional report to pump up Ohr's stock price. *See* ¶¶59-61.

127. Defendants themselves also went to the market and presented at industry conferences and trade shows, gave interviews, and met with analysts to promote the upcoming results of the IMPACT and MAKO Trials. *See* ¶¶49, 64, 68, 73, 74. These actions had the effect of generating enthusiasm for Squalamine and driving up and/or maintaining Ohr's stock price.

128. At the beginning of the Class Period, Ohr had only \$3.4 million in cash on hand and two drug compounds that cost less than \$200,000. *See* ¶41. But through Defendants'



scheme to pump up the stock price with false and misleading statements, the Company was able to conduct four securities offerings during the Class Period through which the Company raised more than \$62 million in less than 4 years. *See* ¶¶52, 62, 72, 105.

**E. The Importance Of Squalamine To Ohr's Success**

129. Because the fraud alleged herein relates to the primary business of Ohr, knowledge of the facts underlying the fraud may be imputed to the Individual Defendants. Indeed, during the Class Period, Squalamine was the Company's sole drug at the clinical trial stage and only hope for a commercialized product. Indeed, Ohr admitted in its SEC filings that it was "substantially dependent on the success of our lead product Squalamine in wet-AMD, which was in a later stage of development than our other product candidates . . . Any delay or setback in the development or regulatory approval of any of our product candidates, but particularly Squalamine in wet-AMD, would likely adversely affect our business[.]" Ohr Pharmaceutical, Inc., Quarterly Financial Report (Form 10-Q) 21 (Feb. 14, 2017). Therefore, the Individual Defendants, as senior level executives, were in such positions at the Company to access all material, non-public information concerning the trials for Squalamine in Wet AMD, and undoubtedly did so given their fiduciary duties.

130. Ohr also had a small number of employees. Thus, it can be presumed that the Individual Defendants, as officers and/or directors, had knowledge of the adverse facts pertaining to the trials for Squalamine in Wet AMD. For instance, Taraporewala described himself as a "[h]ands-on" leader at Ohr and having "*spearheaded*" the development of Squalamine eye drops. Irach Taraporewala, LinkedIn, <https://www.linkedin.com/in/irachtaraporewala/> (last visited June 28, 2018). Also, at all relevant times, the Company's headquarters have been located in New York, New York, where all of its executive officers, and many key directors, resided during the Class Period. *See* Ohr Pharmaceutical, Inc., Annual Report (Form 10-K)

(Dec. 22, 2014); Ohr Pharmaceutical, Inc. Annual Report (Form 10-K) (Dec. 15, 2017). As of September 30, 2014, Ohr had 13 full-time employees, and by September 30, 2017, Ohr only had 4 full-time employees. *See* Ohr Pharmaceutical, Inc., Annual Report (Form 10-K) 8 (Dec. 22, 2014); Ohr Pharmaceutical, Inc., Annual Report (Form 10-K) 7 (Dec. 15, 2017).

### CLASS ACTION ALLEGATIONS

131. Lead Plaintiffs bring this action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of themselves and a class consisting of all persons and entities who purchased or otherwise acquired Ohr common stock in the United States or on the NASDAQ Capital Market between April 8, 2014 and January 4, 2018, inclusive, and were damaged thereby (the “**Class**”).

132. Excluded from the Class are the Defendants named herein, members of their immediate families, any firm, trust, partnership, corporation, officer, director or other individual or entity in which a Defendant has a controlling interest or which is related to or affiliated with any of the Defendants, and the legal representatives, heirs, successors-in-interest or assigns of such excluded persons.

133. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, Ohr common stock was actively traded on the NASDAQ Capital Market exchange, which is an efficient market. While the exact number of Class members cannot be determined at this early stage, given that, as of February 13, 2018, Ohr had 56,466,428 shares of common stock outstanding, Lead Plaintiffs believe that thousands of people bought Ohr common stock during the Class Period. Ohr Pharmaceutical, Inc., Quarterly Financial Report (Form 10-Q) (Feb. 14, 2018). Record owners and other members of the Class may be identified from records maintained by Ohr or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in

securities class actions.

134. Lead Plaintiffs' claims are typical of the claims of the other members of the Class because Lead Plaintiffs and all members of the Class were similarly affected by Defendants' unlawful conduct as complained of herein.

135. Lead Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class action and securities litigation. Lead Plaintiffs have no interests that are contrary to or in conflict with those of the Class.

136. Common questions of law and fact exist as to all members of the Class, and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include, *inter alia*:

- a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;
- b) Whether Defendants' publicly disseminated statements made during the Class Period contained untrue statements of material fact and/or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- c) Whether and to what extent Defendants' material untrue statements and/or omissions of material fact caused the market price of Ohr's common stock to be artificially inflated during the Class Period;
- d) Whether Defendants acted with the requisite level of scienter in omitting and/or misrepresenting material facts;
- e) Whether the Individual Defendants were controlling persons of Ohr;
- f) Whether reliance may be presumed pursuant to the fraud-on-the-market doctrine; and

g) Whether the Class members have sustained damages, and, if so, the proper measure of damages.

137. Lead Plaintiffs know of no difficulty that will be encountered in the management of this action that would preclude its maintenance as a class action.

138. A class action is superior to all other available methods for the fair and efficient adjudication of this action because, among other things, joinder of all members of the Class is impracticable. In addition, since the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation would make it nearly impossible for members of the Class to bring individual actions.

#### **LOSS CAUSATION**

139. Defendants' wrongful conduct, as alleged herein, directly and proximately caused Plaintiffs and the Class to suffer substantial losses.

140. During the Class Period, Plaintiffs and the Class purchased or otherwise acquired Ohr common stock at artificially inflated prices, and were damaged thereby when the truth was revealed and when the risks Defendants concealed with their false and misleading statements materialized. The price of Ohr common stock declined significantly (causing investors to suffer losses) when the Defendants' misrepresentation, and/or information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, and/or the foreseeable risks that had been fraudulently concealed by the Defendants materialized. Those misrepresentations and omissions that were not immediately followed by an upward movement in the Company's stock price served to maintain the share price at artificially inflated levels by maintaining and supporting a false positive perception of Ohr's business, operations, performance, and prospects.

141. Defendants' materially false and misleading statements and omissions misrepresented, the nature of Squalamine's clinical trial results and the likelihood that

Squalamine could successfully treat patients with Wet AMD. These statements misrepresented to investors the risks that Squalamine was faced in being a viable treatment for Wet AMD, which could generate enormous profits for Ohr. When these statements were corrected, and the risks concealed by them materialized, investors suffered losses as the price of Ohr common stock declined.

142. On January 5, 2018, the truth was fully revealed, and the concealed risks fully materialized, when Defendants disclosed that the MAKO results utterly failed, causing investors to suffer losses as the price of Ohr common stock declined \$1.64 per share, from \$2.02 at market close on January 4, 2018 (the prior trading day) to \$0.38 at market close on January 5, 2018 – a one-day decline of 81%. ¶114. For comparison purposes, the S&P 500 Index increased a marginal amount (0.7%) during that time.

143. Accordingly, as a result of their purchases or acquisitions of Ohr's publicly traded common stock during the Class Period, Plaintiffs and other members of the Class suffered economic loss and damages.

### **CONTROL PERSON LIABILITY**

144. The Individual Defendants, because of their positions with Ohr, possessed the power and authority to control the contents of Ohr's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each of the Individual Defendants had a duty to do as follows: (1) promptly disseminate complete, accurate, and truthful information with respect to the Company's clinical trial data; (2) correct any previously issued statements that were materially misleading or untrue when made so that the market could accurately price the Company's securities based upon truthful, accurate, and complete information; and (3) update any previously-issued forward-looking statements that became materially misleading or untrue so that the market could accurately price the Company's

securities based upon truthful, accurate, and complete information. Each of the Individual Defendants was provided with copies of the Company's reports and press releases alleged herein to be false or misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew or recklessly disregarded that the adverse facts and omissions specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations and omissions which were being made were then materially false and/or misleading.

#### **THE FRAUD ON THE MARKET PRESUMPTION**

145. At all relevant times, the market for Ohr's common stock was an efficient market for the following reasons, among others:

- a) Ohr's common stock was listed and actively traded on the NASDAQ Capital Market exchange (ticker symbol OHRP), a highly efficient market;
- b) As a registered and regulated issuer of securities, Ohr filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information;
- c) Ohr regularly communicated with public investors through established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures such as communications with the financial press and other similar reporting services;
- d) The market reacted to public information disseminated by Ohr;
- e) At least 7 analysts followed Ohr's business and wrote reports which were publicly available and affected the public marketplace;

f) The material misrepresentation and omissions alleged herein would tend to induce a reasonable investor to overvalue Ohr's stock; and

g) Without knowledge of the misrepresented or omitted facts, Lead Plaintiffs and other members of the Class purchased Ohr common stock between the time that the Defendants made the material misrepresentations and omissions and the time that the truth was revealed to the market or the concealed risk transpired, during which time the price of Ohr common stock was artificially inflated by Defendants' misrepresentations and omissions.

146. As a result of the above, the market for Ohr securities promptly digested current information with respect to the Company from all publicly available sources and reflected such information in Ohr's stock price. The historical daily trading prices and volumes of Ohr stock are incorporated herein by reference. Under these circumstances, all those who purchased Ohr common stock during the Class Period suffered similar injuries through their purchases of common stock at prices that were artificially inflated by Defendants' misrepresentations and omissions. Thus, a presumption of reliance applies.

#### **NO STATUTORY SAFE HARBOR**

147. The safe harbor provisions for forward-looking statements under the Private Securities Litigation Reform Act of 1995 are applicable only under certain circumstances that do not apply to any of the materially false and misleading statements and omissions alleged in this Complaint.

148. First, none of the identified false and misleading statements and omissions herein are forward-looking statements, but instead are statements of current or historic fact, or are actionable in context because they omit then-existing material facts.

149. Second, many if not all of the identified false and misleading statements herein

were not identified as forward-looking statements.

150. Third, to the extent there were any forward-looking statements that were identified as such at the time made, there were no meaningfully cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Such statements were also not accompanied by cautionary language that was meaningful because any such warnings or “risk” factors contained in, or incorporated by reference in, the relevant press releases, SEC filings, or other public statements described herein were general, “boilerplate” statements of risk that would affect any pharmaceutical development company, and misleadingly contained no factual disclosure of any of the specific details concerning similar important factors that would give investors adequate notice of such risks.

151. Fourth, to the extent there were any forward-looking statements, Defendants are liable for those false and misleading forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, or, by reason of what the speaker failed to note, was materially false and/or misleading, and/or that each such statement was authorized and/or approved by a director and/or executive officer of Ohr who actually knew that each such statement was false or misleading when made.

## **CAUSES OF ACTION**

### **COUNT I**

#### **Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants**

152. Lead Plaintiffs re-allege each allegation above as if fully set forth herein.

153. This Count is brought under Section 10(b) of the Exchange Act (15 U.S.C. § 78j(b)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5), against all Defendants, on behalf of Lead Plaintiffs and all members of the Class.



154. During the Class Period, Defendants violated Section 10(b) and Rule 10b-5 in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Lead Plaintiffs and others similarly situated in connection with their purchases of Ohr common stock during the Class Period.

155. Defendants, individually and in concert, directly and indirectly, by use of means or instrumentalities of interstate commerce and/or of the mails made the false and misleading statements specified herein, including the statements in SEC filings, presentations, press release, conference calls, and analyst reports concerning the Squalamine clinical trial data, whose truth they consciously or recklessly disregarded when they failed to disclose material facts necessary to make the statements made, in light of the circumstances under which they were made, not false or misleading.

156. Defendants, individually and in concert, directly and indirectly, by use of means or instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct to conceal the deficiencies with the Squalamine clinical trial data.

157. Defendants acted with scienter throughout the Class Period because each acted with either the motive and opportunity to deceive, manipulate, or defraud, or with conscious misbehavior or recklessness. Defendants possessed actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with consciously reckless disregard for the truth by failing to ascertain and to disclose such facts even though such facts were available to them or they had a duty to monitor such facts, or deliberately refrained from taking steps

necessary to discover whether the material facts were false or misleading.

158. Ohr is liable for the acts of the Individual Defendants and other Company agents and personnel referenced herein under the doctrine of *respondeat superior*, as those persons were acting or appearing to act as the officers, directors, and/or agents of Ohr in taking the actions alleged herein.

159. Lead Plaintiffs and Class Members purchased Ohr common stock without knowing that Defendants had misstated or omitted material facts about the clinical trial data for Squalamine. In so doing, Lead Plaintiffs and Class members relied on false and misleading statements made by Defendants, and/or an absence of material adverse information that was known to Defendants or recklessly disregarded by them but not disclosed in Defendants' public statements.

160. Lead Plaintiffs and other Class members have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Ohr common stock, which inflation was removed from the prices of their shares when the truth became known. Lead Plaintiffs and the Class would not have purchased Ohr common stock at the prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by Defendants' materially false and misleading statements.

161. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and other Class members suffered damages in connection with their purchases or acquisitions of Ohr common stock during the Class Period as the truth was revealed or concealed risks transpired.

**COUNT II**  
**Violations of Section 20(a) of the Exchange Act**  
**Against the Individual Defendants**

162. Lead Plaintiffs re-allege each allegation above as if fully set forth herein.

163. This Count is brought under Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), against all of the Individual Defendants, on behalf of Lead Plaintiffs and all members of the Class.

164. During their tenures as officers and/or directors of Ohr, each of the Individual Defendants acted as controlling persons of Ohr within the meaning of Section 20(a) of the Exchange Act. By reason of their status as senior executive officers and/or directors of Ohr, the Individual Defendants had the power and authority to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein. Each of the Individual Defendants was able to and did control, directly and indirectly, the content of the public statements made by the Company during the Class Period, including the statements Lead Plaintiffs allege are false and misleading, thereby disseminating the false and misleading statements and omissions of fact alleged herein.

165. By virtue of their high-level positions at Ohr, and as more fully described above, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company. The Individual Defendants were able to and did influence and control Ohr's decision-making, including reviewing and controlling the content and dissemination of the documents that Lead Plaintiffs and the Class contend contained materially false and misleading information and on which Lead Plaintiffs and the Class relied. The Individual Defendants were also in the position to prevent the issuance of these statements or to correct them prior to dissemination. Thus, the Individual Defendants were culpable participants in Ohr's fraud.

166. As set forth in Count I, Ohr committed a primary violation of Section 10(b) of the Exchange Act by knowingly and/or recklessly employing devices, artifices, and schemes to defraud, disseminating materially false and misleading statements and/or omissions, and/or

engaging in acts, practices, or a course of conduct that operated as a fraud or deceit upon Lead Plaintiffs and the Class throughout the Class Period. By virtue of their positions as controlling persons of Ohr and as a result of their own aforementioned wrongful conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as the Company is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

167. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiffs and the Class suffered damages in connection with their purchases of Ohr common stock.

#### **JURY TRIAL DEMAND**

168. Lead Plaintiffs hereby demand a trial by jury on all triable claims.

#### **PRAYER FOR RELIEF**

WHEREFORE, Lead Plaintiffs demand judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Lead Plaintiffs as the Class representatives and Lead Counsel as Class Counsel;
- B. Requiring Defendants to pay damages sustained by Lead Plaintiffs and the Class by reason of the acts and statements alleged herein;
- C. Awarding Lead Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs;
- D. Awarding rescissory damages in favor of Lead Plaintiffs and the other Class members where appropriate against all Defendants, jointly and severally, for all injuries sustained as a result of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law; and
- E. Awarding such other and further relief as this Court may deem just and proper.

Dated: August 7, 2018

Respectfully submitted,

By: /s/ Richard W. Gonnello  
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